

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

Civil Case No.: 1:14-cv-13155-IT

EBONIA ELLIOTT-LEWIS  
Individually and as Relator, and the  
UNITED STATES OF AMERICA,

Plaintiffs/Relators

**Leave to file granted on  
May 5, 2017**

ABBOTT LABORATORIES, INC.,

Defendant.

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**PLAINTIFF'S FIRST AMENDED COMPLAINT**

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RELATOR, Ebonia Elliott-Lewis ("Elliot-Lewis"), brings this First Amended Complaint in the name of the United States of America, by and through her undersigned attorney, David P. Angueira, and alleges as follows.<sup>1</sup>

**PARTIES**

1. Relator, Elliott-Lewis is a citizen of the state of Massachusetts.
2. Defendant, Abbott Laboratories ("Abbott") is a duly organized corporation with a principle place of business at 100 Abbott Park Road, Abbott Park, Illinois. It maintains offices in Massachusetts. It routinely conducts business and accepts correspondence at its Massachusetts address.

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<sup>1</sup> Because of the impoundment order entered by this Court, all attachments and other supporting documents to the complaint have not been filed with this complaint but will be made available to the Court if necessary.

### **JURISDICTION AND VENUE**

3. This action arises under the False Claims Act, 31 U.S.C. § 3729 *et seq.*
4. This Court maintains subject matter jurisdiction over this action pursuant to 31 U.S.C. § 3732 (a) (False Claims Act) and 28 U.S.C. § 1331 (Federal Question).
5. Venue is proper in this Court pursuant to 31 U.S.C. § 3732 (a) because: (i) Abbott resides in this district; (ii) Abbott transacts business in this district and did so at all time relevant to this complaint; and, as averred below, (iii) Abbott committed acts proscribed by 28 U.S.C. § 3729 – acts giving rise to this action – within this district.
6. Before filing this complaint, Elliott-Lewis served a copy of this complaint upon the United States, together with a written disclosure statement setting forth and enclosing all material evidence and information they possess, pursuant to the requirements of 31 U.S.C. § 3730 (b)(2).
7. Elliott-Lewis has complied with all other conditions precedent to bringing this action.
8. Elliott-Lewis is the original source of, and has direct and independent knowledge of all allegations herein and has voluntarily provided such information to the Government.

### **A. INTRODUCTION**

9. This complaint alleges violation of the False Claims Act (FCA) under fraud in the inducement, actual presentment and conspiracy theories of liability as well as violation of the anti-kickback statutes and Public Policy Rule exception. Plaintiff alleges Abbott Laboratories conspired to and did use illegal promotional practices

to induce submitting entities to submit false and fraudulent claims to the United States government for payment. The false claims pertain to two (2) different Abbott product families: XIENCE drug-eluting stents and Bioresorbable Vascular Scaffolds (BVS). Both products are class III, significant risk implants that are subject to the premarket approval (PMA) regulatory process. Abbott's misconduct caused false claims to accrue based on two (2) separate and distinct legal theories related to criminal violations of the Food, Drug, and Cosmetic Act (FDCA) that implicate FCA liability:

10. THEORY #1: Off-label promotion is evidence of criminal misbranding under the FDCA and noncompliance with misbranding requirements attaches FCA liability  
XIENCE is a commercial product, so that portion of this case contains a typical, off-label promotion allegation. XIENCE stents were illegally promoted "off-label" for patients with diabetes mellitus to induce false and fraudulent claims from March 25, 2014-September 22, 2015. Promotion is evidence of intent to "misbrand." Abbott was not authorized to engage in XIENCE promotion for diabetes mellitus until September 2015, when FDA approved that indication based on Abbott's PMA supplement submission. The United States incurred damages associated with XIENCE stent claims for 40,000 misbranded devices that were ineligible for federal funds.
11. THEORY #2: Compliance with Federal regulations relating to the protection of human subjects is a material precondition for payment and noncompliance attaches FCA liability

Bioresorbable Vascular Scaffold (BVS) is an unapproved medical implant that is not yet commercially available. Abbott intentionally and repeatedly engaged in the illegal promotion of this unapproved medical implant to healthcare professionals for a clinical use other than the intended use. This misconduct is tantamount to initiating unregulated human medical experimentation because Abbott did not first obtain an investigational device exemption (IDE) for a clinical use that the company promoted.

Typically, with off-label promotion cases, the promotion is proof of intent to "misbrand" a medical product. No such requirement exists for BVS since Abbott made false and misleading statements about the product when it had NO FDA-approved use (and no FDA-approved labeling). BVS is in a pivotal trial in the US and Medicare patients represent 40% of the 5000 human subjects in the clinical trials. Medicare pays the routine clinical trial costs for these study participants under the National Coverage Determination for Routine Costs in Clinical Trials (NCD 310.1). These are false and fraudulent claims because Abbott violated human subject protection regulations.

Preapproval promotion is evidence of criminal solicitation to commit medical battery and, unlike off-label promotion, preapproval promotion is an expressly "prohibited act" under 21 CFR 812. In addition, 21 CFR 812 is a human subject protection regulation. BVS clinical trials were not conducted in compliance with Federal regulations relating to the protection of human subjects and compliance is a material precondition for payment. Statements describing that compliance is a precondition for payment can be found in the Medicare Benefits Policy Manual at

Chapter 14, in the National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1), and in the Federal Policy for the Protection of Human Subjects ("Common Rule") under title 45 CFR part 46, subpart A (section 46.122).

12. Relator alleges that Abbott Laboratories violated the following federal regulations and that these violations attach False Claims Act (FCA) liability:

45 CFR 46, subpart A

21 CFR 56

21 CFR 50

21 CFR 801

21 CFR 812

21 CFR 814

13. Abbott Laboratories also violated the Anti-Kickback Statute (AKS) when the company used kickback payments to induce submitting entities to submit false and fraudulent claims to the United States government for payment. The false claims pertain to two (2) different Abbott product families: XIENCE drug-eluting stents and Bioresorbable Vascular Scaffolds (BVS).

**B. XIENCE STENTS WERE ILLEGALLY PROMOTED “OFF-LABEL” FOR PATIENTS WITH DIABETES MELLITUS TO INDUCE FALSE AND FRAUDULENT CLAIMS**

14. Relator alleges that Abbott engaged in the off-label promotion of its FDA-approved, drug-eluting stent XIENCE for use in diabetic patients beginning in March 2014, which is evidence of intent to misbrand. At the time that this promotion occurred, XIENCE did not have an indication for use in diabetic

patients. FDA granted XIENCE the diabetes mellitus indication on September 23, 2015 (see the premarket approval supplement under PMA number P070015 S128A). Relator alleges that Abbott introduced misbranded XIENCE stents into interstate commerce during the 17-month period from March 25, 2014 to September 22, 2015.

15. During that period Abbott made \$600 million in revenue on XIENCE domestically. Abbott illegally disseminated misleading information to 2500 targeted physicians of the 6500 US interventional cardiologists and relator alleges that these targeted physicians implanted 80% of the XIENCE devices for which Abbott received revenue during the period.
16. Medical device manufacturers involved in the distribution of devices must follow certain requirements and regulations once devices are on the market. These include such things as tracking systems, reporting of device malfunctions, serious injuries or deaths, and registering the establishments where devices are produced or distributed. Postmarket requirements also include postmarket surveillance studies required under section 522 of FDCA as well as post-approval studies required at the time of approval of a premarket approval (PMA). To help assure the continued safety and effectiveness of an approved device, a post-approval study may also be required as a condition of approval under 21 CFR 814.82(a)(2). A post-approval study may be a clinical study required in the PMA approval order and is intended to gather specific information to address questions about the postmarket performance of or experience with an approved medical device.

17. The data collected in the USA Post-Approval Study XIENCE V USA (NCT00676520) provides reliable information to support relator's allegation that false claims were actually submitted to the government since 35.6% of the study patients were diabetic.
18. Based on a peer-reviewed 2010 publication called *Insurance type influences the use of drug-eluting stents* (Gaglia et al 2010), 45.2% of percutaneous coronary intervention (PCI) with stenting patients had Medicare while 3.7% had Medicaid. Based on this information, the United States government incurred more than \$70 million in damages associated with XIENCE stent claims for misbranded devices that were ineligible for federal funds.
19. There are 700,000 stents implanted annually in the United States. Therefore 990,000 of these stents were used during the 17-month period in the US:  
$$990,000 * (0.35 \text{ market share Xience}) * (.80 \text{ share of XIENCE due to physicians solicited}) * (0.30 \text{ share of diabetics}) * (0.452 \text{ share of Medicare})$$
  
**= 37,500 ineligible Xience stents paid by Medicare from 03/25/2014-09/22/2015**  
$$990,000 * (0.35 \text{ market share Xience}) * (.80 \text{ share of XIENCE due to physicians solicited}) * (0.30 \text{ share of diabetics}) * (0.037 \text{ share of Medicaid})$$
  
**= 3000 ineligible Xience stents paid by Medicaid from 03/25/2014-09/22/2015**
20. Based on these data, each of the 2500 physicians Abbott targeted with illegal promotional material contributed an average of 15 ineligible Xience stents to a total of 40,000 stents that were ineligible for federal funds when the claims for payment were submitted to Medicare and Medicaid. Relator alleges these XIENCE stents and related services were reimbursed based on false claims and

that these claims do not meet the definition of “reasonable and necessary” as defined by 42 U.S.C. 1395y. The Centers for Medicare & Medicaid Services (CMS) excludes coverage for devices and related services that have not been authorized for marketing by FDA.

21. Representative false claims include claims from 03/2014 to 9/2015 for XIENCE stents implanted in patients with a diabetes mellitus diagnosis by the 2500 physicians who received Abbott’s illegal promotional material. The list of physician National Provider Identifiers (NPI) shown in Appendix A includes physicians on the list of 2500 newsletter recipients as submitting entities for these false claims. The disseminated material was promotional and misleading because it fails to provide a “fair balance” of information about *risks* as compared with information about benefits for use in patients diagnosed with diabetes mellitus.
22. Relator alleges that Abbott intentionally and repeatedly violated labeling requirements found at part 801 (see Sec. 801.6 Medical devices; misleading statements):  
  
*Among representations in the labeling of a device which render such device misbranded is a false or misleading representation with respect to another device or a drug or food or cosmetic.*
23. Relator alleges that Abbott’s promotional newsletters constitute labeling that violates federal regulations found at 21 CFR 801 (see Sec. 801.4, Sec. 801.5, and Sec. 801.6):

1. “Recent Clinical Data for Metallic Drug-Eluting Stents (DES) and Bare Metal Stents (BMS) from Major Meta-Analysis Studies” (Abbott routing number SE2939496 Rev. B 03/14)
2. “Recent Clinical Data for Durable and Bioresorbable polymer Drug-Eluting Stents (DES) and Bare Metal Stents (BMS) from Major Meta-Analyses Studies” (Abbott routing number SE2940007 Rev. A 07/14)
24. In 2012, the RESOLUTE zotarolimus-eluting coronary stent (Medtronic) became the first drug-eluting stent approved by the FDA for use in patients with diabetes. Among representations in the labeling of XIENCE which render XIENCE misbranded is misleading representation with respect to another device called the RESOLUTE zotarolimus-eluting coronary stent (Medtronic). The newsletters are misleading because they imply that XIENCE, a stent with no FDA-approved diabetes indication, produces better clinical outcomes with respect to stent thrombosis in diabetic patients compared to a device that was FDA-approved and labeled for that population of patients. This comparison erroneously suggests that as of March 2014, like RESOLUTE, XIENCE was also FDA-approved for patients with diabetes.
25. Abbott was required to conduct and submit specific testing regarding stent thrombosis as a condition under which the PMA was granted. Abbott was also required to submit a PMA supplement to seek a labeling change for a diabetes mellitus indication before making promotional comparisons between XIENCE and another device (e.g. RESOLUTE) approved for this population of patients.

Abbott was not authorized to engage in XIENCE promotion for diabetes mellitus until September 2015, when FDA approved that indication.

26. There are clear admissions by Abbott leadership that implicate misbranding and they constitute knowing and willful misconduct in criminal violation of FDA-mandated terms under which PMA number P070015 was granted. Promotional material that Abbott disseminated beginning in March 2014 was intended to induce XIENCE referrals for an indication for use in diabetics that was not granted by FDA until September 2015 (after relator's qui tam lawsuit was filed). False claims accrued from 3/2014 to 9/2015 because Abbott did not meet FDA's expressed PMA ("conditions of approval") requirements for XIENCE, Abbott promoted XIENCE off-label for diabetes, and the company subsequently introduced misbranded XIENCE stents into interstate commerce for sale in the US that were ineligible for coverage using Federal funds.
27. Abbott also used kickbacks to induce physician recipients of the illegal promotional materials to submit false, fraudulent XIENCE claims and the details of these tactics are described later in this complaint.

**C. BIORESORBABLE VASCULAR SCAFFOLD (BVS) CLINICAL TRIALS  
WERE NOT CONDUCTED IN COMPLIANCE WITH FEDERAL  
REGULATIONS RELATING TO THE PROTECTION OF HUMAN  
SUBJECTS WHICH IS A MATERIAL PRECONDITION FOR PAYMENT**

28. False Claims Act enforcement is warranted in this qui tam case because of ethical violations committed by Abbott Laboratories:

1. Abbott deceived medical professionals by making false and misleading statements, both in print and in continuing medical education (CME) settings, that promote the illegal implantation of an unapproved medical device.
  2. Abbott's promotional campaign encouraged medical professionals to perform an illegal medical procedure for which patients (human subjects) cannot grant valid informed consent.
  3. Medicare patients in Abbott's Bioresorbable Vascular Scaffold (BVS) clinical trials include elderly people. The World Health Organization (WHO) describes the elderly as a "vulnerable group," where vulnerability is the degree to which a population is unable to anticipate, cope with, resist and recover from the impacts of disasters. Due to Abbott's misconduct, this vulnerable population was exposed to unnecessary risks in violation of Federal human subject protection regulations.
29. Relator alleges that Abbott intentionally and repeatedly engaged in the illegal promotion of an *unapproved* medical implant to healthcare professionals for a clinical use *other than* the intended use. This misconduct is tantamount to initiating unregulated human medical experimentation because Abbott did not first obtain an investigational device exemption (IDE) for a clinical use that the company promoted. Promotion, marketing, and advertising campaigns are implemented to encourage specific behaviors. Abbott's promotion (solicitation) encouraged healthcare professionals to engage in an illegal act. By promoting implantation of an unapproved medical device for an unauthorized medical use,

- Abbott solicited healthcare professionals to engage in an intentional, unauthorized, offensive touching (medical battery) of human subjects, including Medicare patients, in the Bioresorbable Vascular Scaffold (BVS) clinical trials.
30. The Food and Drug Administration (FDA) is a U.S. Department of Health and Human Services (HHS) agency that regulates clinical investigations of products under its jurisdiction, such as drugs, biological products, and medical devices. FDA regulations are published as part of chapter 21 of the Code of Federal Regulations (CFR), and FDA's human subject protection regulations are in parts 50, 56, and 812.<sup>1,2,3</sup> The HHS human subject protection regulations codified in 45 CFR part 46,<sup>4</sup> under subpart A, are also known as the Federal Policy or the "Common Rule." Pursuant to §46.122 *Use of Federal funds*. *Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.* The Common Rule and other key documents are important to the ethical and legal underpinnings in this lawsuit, including: Medical Device Amendments (MDA) of 1976 to the Federal Food, Drug, and Cosmetic Act, FDA/HCFA Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices, and National Coverage Determination (NCD 310.1) for Routine Costs in Clinical Trials.
31. This qui tam case contains an exception to the doctrine of informed consent: no patient can grant a physician valid consent to implant an unapproved, class III, significant risk medical device without an IDE (i.e. without the backing of FDA controlling legal authority). A patient cannot offer valid consent for this type of

implantation because the underlying medical procedure is itself a crime. A physician engaged in such conduct without proper regulatory approval (and required IRB oversight) commits an illegal act called “medical battery” on a patient. FDA, as the controlling legal authority, can neither adequately monitor nor appropriately enforce regulations regarding human medical experiments about which it has no knowledge. For these reasons, class III significant risk medical devices including the vascular stents and scaffolds in this complaint, must comply with all elements of 21 CFR 812, including the requirements that prohibit preapproval promotion (found at 21 CFR 812.7). The requirements at 21 CFR 812 are part of the human subject protection regulations described in the Common Rule.

32. National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1),<sup>5</sup> which was implemented in the year 2000 and updated in July 2007, states that compliance with human subject protections is a condition of payment because a clinical trial qualified for Medicare coverage of routine costs is presumed to meet these characteristics:

*The trial is in compliance with Federal regulations relating to the protection of human subjects; and*

*All aspects of the trial are conducted according to the appropriate standards of scientific integrity.*

33. The NCD also describes the Qualification Process for Clinical Trials whereby clinical trials that meet the qualifying criteria will receive Medicare coverage of

routine costs after the trial's lead principal investigator certifies that the trial meets the criteria.

34. Under the Food, Drug, and Cosmetic Act (21 U.S.C. 360c) devices fall into one of three classes. To assist CMS under this categorization process, the FDA assigns one of two categories to each FDA-approved investigational device exemption (IDE). Category A refers to experimental IDEs, and Category B refers to non-experimental IDEs. The Bioresorbable Vascular Scaffold (BVS) clinical trials are conducted under an IDE (G120002) that FDA approved under Category B in December 2012, just 17 years after Medicare began covering this type of study. (see Federal Register /Vol. 78, No. 32/Friday, February 15, 2013/Notices on pg. 11197)

***Illegal Promotion of an Unapproved Medical Device***<sup>6,7,8,9,10</sup>

35. Abbott, as the study sponsor, sought Medicare coverage to defray the high product development cost associated with bringing this new technology to market. This lawsuit alleges severe ethics violation that were both detected and reported for enforcement for the first time by a whistleblower.
36. None of the clinical trials conducted for the Bioresorbable Vascular Scaffold (BVS) device meet the NCD qualifying criteria because the sponsor knowingly violated Federal regulations relating to the protection of human subjects. In other words, all BVS clinical trials are conducted in violation of Human Subject Protection Regulations due to the sponsor's misconduct and these violations have been supported using federal funds in the form of Medicare reimbursement. The Common Rule expressly prohibits use of federal funds in support of Human

Subject Protection Regulation violations pursuant to §46.122 *Use of Federal funds. Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.*

37. BVS clinical trials were initiated to collect evidence in support of a regulatory submission so that Abbott can obtain permission to legally market a medical implant for profit. Medicare covers the routine costs related to clinical trials that meet the qualifying criteria. The BVS clinical trials do not meet the qualifying criteria. Due to Abbott's misconduct as a clinical trial sponsor, all BVS claims are false because the studies are not conducted in compliance with human subject protection regulations.

***Defining Promotion***

38. FDA granted Abbott an Investigational Device Exemption (IDE)<sup>11</sup> on 12/14/12 that allows the company to perform human research about the use of BVS technology for treating heart disease (specifically coronary artery disease). BVS is an implant and a class III, significant risk medical device that presents a potential for serious risk to the health, safety, or welfare of a subject. No FDA-approved labeling has been granted for use of this technology, but Abbott is already promoting BVS for treating heart disease and peripheral vascular disease. Abbott has repeatedly presented promotional material containing statements that are not consistent with the device's FDA-approved labeling (since no such labeling has been granted at this time).

39. For these reasons, Abbott presentations<sup>12,13,14</sup> constitute health fraud and illegal promotion:

1. **Control of presentation content and selection of presenters** - presentation materials were developed by Abbott and routed for company approval; the presenters were Abbott employees
2. **Disclosures**: VIVA 2013 speaker was an Abbott employee but failed to disclose any financial relationships with Abbott
3. **Program focus** - the brand name "BVS" was incorporated into the VIVA event title; Abbott's influence over Continuing Medical Education (CME) content is unethical based on independent standards outlined by the Accreditation Council for Continuing Medical Education (ACCME) online at <http://www.accme.org/>
4. **Abbott's relationship with the event provider**:
  - Abbott paid both the VIVA speaker and the VIVA conference CME event organizer
  - Abbott paid the LINC and CRT conference speakers
  - Medstar Washington Hospital Center received funds from Abbott<sup>15</sup> as the CRT conference CME event accreditation sponsor and a clinical trial site for both the ABSORB III and ABSORB IV clinical trials. For example, CMS Open Payments shows Abbott made a \$350,000 payment to Washington Hospital Center during reporting year 2014 (reference Transaction ID 196912330 at [openpaymentsdata.cms.gov](http://openpaymentsdata.cms.gov)).

Relator alleges Transaction ID 196912330 is a kickback payment from Abbott to the Medstar Washington Hospital Center.

5. **Abbott's involvement in marketing messaging**: Unsubstantiated superiority statements made at LINC 2013 were reiterated in a CRT 2013 conference presentation by an Abbott senior executive and appeared again in a VIVA 2013 talk by an Abbott employee who made no financial disclosure. These presentations were developed by Abbott.
6. **Abbott's history of misconduct**: Abbott received an FDA warning letter for illegal promotion of another significant risk implant at the same VIVA conference event in 2007
7. **Multiple presentations**: multiple conference presentations re-stated the same unsubstantiated superiority statements, which constitutes a marketing campaign
8. **Audience selection** - VIVA conference was targeted at leg specialists (peripheral)
9. **Post-activity dissemination of "enduring materials"** - faculty role of Abbott employees means the presentation materials were disseminated online by the conference organizer to thousands of registered participants (Abbott's company policy prohibits employees from influencing CME content in this manner, but the company broke its own rules for financial gain)

10. **Ancillary promotional activities** - Abbott continued to proactively disseminate company-developed newsletters containing promotional content
40. ABSORB BVS was granted IDE category B status, which includes class III devices where the incremental risk is the primary risk in question. FDA provides the category determination on the IDE approval letter to the sponsor and also forwards this information to Centers for Medicare & Medicaid Services (CMS). For category B, the underlying questions of safety for that device type are presumed to be understood based on the risk profile of other devices in the class. For example, in a XIENCE premarket approval letter<sup>16</sup>, FDA explicitly identifies the risk of thrombosis as a critical concern for the device class.
41. Abbott also uses company-generated newsletters to disseminate illegal promotional information and reinforce marketing messages<sup>17,18,19,20,21</sup>. This material is promotional because it overstates efficacy and omits safety risks associated with Abbott products.

***Pre-approval Promotion violates Federal Human Subject Protection Regulations***

42. Relator reported in her internal complaint that Abbott Medical Affairs executives were trying to convince the Office of Ethics and Compliance to change policy restrictions on company employees influencing CME content. Abbott Medical Affairs executives had already successfully convinced the Abbott legal department to allow them to develop a newsletter that was used to support marketing goals. The XIENCE newsletter submitted in relator's disclosure was proactively disseminated to physicians who had a contractual relationship with the

company, representing about 2500 recipients with roles including speakers, consultants, and clinical trial investigators. Relator was terminated because of her protected activity regarding human subject protection regulations. Even after her compliance report about the False Claims Act violation, Abbott Medical Affairs executives continued to distribute illegal promotional material including a BVS newsletter about safety concerns raised by the GHOST-EU registry findings<sup>22</sup>: Capodanno, Davide, et al. "Percutaneous coronary intervention with everolimus-eluting bioresorbable vascular scaffolds in routine clinical practice: early and midterm outcomes from the European multicentre GHOST-EU registry." EuroIntervention [Epub ahead of print] (2014).

43. The GHOST-EU research conclusion states, "'Real-world' outcomes of BVS showed acceptable rates of TLF at six months, although the rates of early and midterm scaffold thrombosis, mostly clustered within 30 days, were not negligible." Abbott responded with an investigational device-focused newsletter titled "Pre-TCT 2014: Absorb Fully Bioresorbable Vascular Scaffold (BVS): Emerging Real-World Clinical Data and Optimal Implant Techniques." This newsletter is promotional because it does not give a "fair balance" of information about risks since it was not accompanied by FDA-approved BVS product labeling.
44. Abbott presented promotional material containing unsubstantiated superiority statements about an investigational medical device without supporting clinical evidence at continuing medical education conference events, including VIVA 2013, CRT 2013, and LINC 2013.

45. In violation of 21CFR812.7, Abbott represents that an investigational device is safe or effective for the purposes for which it is being investigated” by:
1. comparing an investigational device (BVS) to other FDA-approved devices
  2. making unsubstantiated superiority statements about an investigational device: BVS is the “preferred solution for best outcomes”
  3. describing an investigational device as superior in a clinical application for which neither an IDE nor premarket approval nor labeling was granted: peripheral vessel disease in the leg
46. Relator alleges that Abbott intentionally and repeatedly violated labeling requirements found at 21 CFR part 812 (see Sec. 812.5 Labeling of investigational devices):
- (b) Prohibitions. The labeling of an investigational device shall not bear any statement that is false or misleading in any particular and shall not represent that the device is safe or effective for the purposes for which it is being investigated.*
47. Relator alleges that Abbott intentionally and repeatedly violated labeling requirements found at part 801 (see Sec. 801.6 Medical devices; misleading statements):
- Among representations in the labeling of a device which render such device misbranded is a false or misleading representation with respect to another device or a drug or food or cosmetic.*
48. Unsubstantiated superiority statements appear in an interventional cardiology course presentation at LINC 2013 titled “REVOLUTION IN SFA TREATMENT

TECHNOLOGY.” The same unsubstantiated superiority statements in the VIVA presentation were obtained from yet another presentation made by an Abbott senior executive at yet another CME event in February: note that in the slides, the presenter cites “Rapoza, CRT 2013.” The same unsubstantiated superiority statements were also presented at the Cardiovascular Research Technologies (CRT) conference event in February 2013. The conference presentations were disseminated over the internet as enduring materials to all registered users of the websites at <http://www.crtonline.org/> and <http://vivaphysicians.org/>. None of these presentations were accompanied by FDA-approved BVS product labeling or risk information.

49. Abbott's promotional pieces are misleading because they imply that BVS offers a clinical advantage over other commercially available medical devices including Percutaneous Transluminal Angioplasty (PTA), Drug-Coated Balloon (DCB), Arthrorectomy, and Metallic Stents. On a slide titled “Clinical Goals of Minimally Invasive SFA Treatment” Abbott shows “Minimize long term thrombosis risk” as one of the “Long Term Outcomes.” On a later slide in the presentation, Abbott describes the “Clinical Impact of SFA Treatment Modalities” showing BVS is the “preferred solution” for “best outcomes” compared to PTA, DCB, Arthrorectomy, Metallic Stents. These statements are unsubstantiated promotional claims because none of Abbott's cited references describe any clinical trial data comparing BVS to any other medical devices to support statements of superiority in superficial femoral artery (SFA) or peripheral disease treatment in the leg. Abbott’s promotional material is misleading because it implies that BVS *minimizes*

*thrombosis risk* compared to PTA, DCB, Arthroectomy, Metallic Stents when used as a therapy for vessel disease in the leg.

50. In the Pre-TCT BVS newsletter, Abbott says, “Proper use of these techniques can ensure lower event rates in complex lesions.” Regarding the GHOST-EU research conclusion that rates of scaffold thrombosis are not negligible, Abbott also says, “[G]iven the small sample sizes and lack of a randomized control group, and many being retrospective with varying durations of follow-up, the clinical evidence is too early to make any conclusions about low-frequency events like stent thrombosis.” Without substantiating evidence or premarket approval, Abbott made superiority statements about BVS peripheral outcomes compared to other devices. However, when independent researchers led by Capodanno raise safety concerns about BVS thrombosis rates, Abbott says more evidence is necessary since “clinical evidence is too early to make any conclusions. Abbott made conclusory statements about BVS safety and efficacy in peripherals despite the lack of clinical evidence when the goal was to drive profitability.
51. Similarly, in the “Update on Absorb from TCT 2014” newsletter, Abbott makes predictive promotional claims that the “seminal finding” of a lower angina rate for the BVS implant “will be confirmed in ABSORB III and prospectively in ABSORB IV.” This claim is promotional because the BVS studies were not complete in 2014; therefore, the statement cannot be supported with substantial evidence. The newsletter is dated October 2014, which is the same month as the announcement of the first FDA-approval for a drug-coated balloon<sup>23</sup> (DCB) used for treating vessel blockages in the leg (including the superficial femoral artery).

DCBs represent a potential competitive threat to scaffold adoption and market share. Abbott's illegal promotion is executed to help meet commercial objectives.

52. Abbott does not have substantial clinical evidence to support these comparisons, which were shown in the CME presentations given by Abbott employees:
  1. BVS is the preferred solution for best peripheral outcomes versus PTA.
  2. BVS is the preferred solution for best peripheral outcomes versus DCB.
  3. BVS is the preferred solution for best peripheral outcomes versus Arthroectomy.
  4. BVS is the preferred solution for best peripheral outcomes versus Metallic Stents.
53. Making statements that the investigational BVS device, a class III, significant risk implant, is superior to other FDA-approved devices without substantial evidence constitutes promotion.
54. In February 2013, Abbott met with Medicare about how to secure federal reimbursement for the BVS clinical trials and an illegal CRT 2013 conference presentation occurred during that same month. CRT 2013 conference attendees could receive CME credits under the ACCME accreditation of the conference sponsor: MedStar Washington Hospital Center. MedStar Washington Hospital Center is also an BVS clinical trial site that conducts human research under a Federalwide Assurance (FWA) for the Protection of Human Subjects (see FWA00000504).
55. Every BVS clinical trial site with a FWA of compliance with 45 CFR 46, like MedStar Washington Hospital Center, has made a false statement of material fact

(in certifying that the trial is conducted in compliance with Human Subject Protection Regulations) due to Abbott's misconduct.

56. Specifically, under 45 CFR 46, subpart A:

*§46.103 (a) Each institution engaged in research which is covered by this policy and which is conducted or supported by a federal department or agency shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements set forth in this policy.*

*§46.101 (e) Compliance with this policy requires compliance with pertinent federal laws or regulations which provide additional protections for human subjects.*

57. FDA oversight for the conduct of device research complements basic regulatory requirements for the protection of human subjects with the addition of specific regulatory requirements for devices. The requirements in 21 CFR 812 provide additional protections for human subjects. According to 45 CFR 46, subpart A: *§46.122, "Use of federal funds: Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied."*

58. Compliance with human subject protection regulations is a precondition of federal payments such as Medicare reimbursement for clinical trials. Abbott has knowingly failed to comply by using various forms of misconduct to secure Medicare reimbursement for claims that are ineligible for payment using federal funds.

59. Despite the lack of FDA-approval, Drs. Chuck Simonton and Krishna Sudhir, Abbott senior executives, directed the relator, a subordinate specifically assigned to Medical Science activities in the United States, to “Increase ABSORB’s penetration into PCI market” in writing as part of the goals and objectives upon which salaries are based. At that time ABSORB was an unapproved medical implant and increasing market penetration of an unapproved medical implant is illegal since only clinical investigators are authorized to use the product (and only within the scope of the FDA-approved IDE). The egregious misconduct in this complaint includes presentations by paid employees at CME events funded by large Abbott grants.

***Evidence of Kickback Law violations***

60. Those CME grants and payments to employees presenting and creating these illegal promotional materials, which are intended to induce referrals paid for by federal programs, are kickbacks (see 42 U.S. Code § 1320a–7b):
- “Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—*
- (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or*
- (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty...”*

61. The Abbott employees described in this complaint do not fall under the Anti-kickback Statute safe harbor<sup>24,25</sup> because they were directed and paid to increase referrals of an unapproved medical device, which is illegal. Abbott's salary payments to these employees are not protected by the employee exception because that provision only protects payments "for employment in the provision of covered items or services." BVS is not FDA-approved so promoting BVS is not protected. Abbott's pre-approval promotion of a heart disease device for treating vessel disease in the leg allows the company to usurp the human agency of each patient implanted with its new device.
62. Preapproval promotion is expressly prohibited under the Federal Food, Drug, and Cosmetic Act (FDCA) because it is an inchoate offense: preapproval promotion is a unique type of solicitation. By executing a fraudulent scheme to promote an unapproved medical implant for a new use (peripheral vascular disease) other than the intended use (heart disease), Abbott engaged in petitioning physicians to commit "medical battery" on BVS clinical trial subjects before the first Medicare claim was submitted. Abbott intended to cause "unauthorized, offensive contact" with patients in the form of invasive medical implantation. No proof of intent to inflict harm is required for a showing of FCA liability in this case because every medical professional Abbott solicited to perform an illegal medical procedure is a potential principal in attempting and perpetrating a criminal act. Abbott also engaged in additional solicitation after this lawsuit was filed in August 2014. In fact, Abbott disseminated these illegal promotional newsletters to US physicians with no accompanying FDA-approved labeling or risk information:

1. “Pre-TCT 2014 Absorb™ Fully Bioresorbable Vascular Scaffold (BVS): Emerging Real-World Clinical Data and Optimal Implant Techniques” (SE2940254 Rev. A 09/14)
  2. “Update on Absorb™ from TCT 2014” (SE2940457 Rev. A 10/14)
63. Abbott’s intent to encourage the “unauthorized, offensive contact” is also evident by the company’s targeted promotion of an unapproved *heart* disease implant to *peripheral* vascular specialists at *peripheral* CME events: these facts are sufficient to render the Medicare claims false because Abbott Laboratories did not protect the rights, safety, and welfare of human subjects as required by law.
64. Even the brand name Abbott picked for the product, “Bioresorbable Vascular Scaffold” was intended to sound like the name of a product category. This marketing tactic is clearly a ploy from which Abbott benefited because the BVS name appeared repeatedly in CME session titles (see section 3.7, Timeline), secretly converting CME program agendas into Abbott BVS marketing collateral. Examples of Abbott-developed promotional presentation titles created for and presented at CME events include: “Development Of Bioresorbable Scaffold Platforms For The Peripheral Vasculature: Can The Excellent Coronary Results Of The ABSORB TRIAL With Everolimus Polylactide Be Duplicated In Peripheral Arteries,” “BVS – the future of PAD treatment,” and “Bioresorbable Vascular Scaffolds: The Next Greatest Thing.” In a 2009 scientific publication authored by company employees, Abbott states, “Bioresorbable polymeric vascular scaffolds may spawn a fourth revolution in percutaneous coronary intervention (PCI) and a novel treatment termed vascular restoration therapy. The

principal design considerations for bioresorbable scaffolds are discussed in the context of physiological behaviour using the Bioabsorbable Vascular Solutions (BVS) ABSORB Cohort B scaffold (Abbott Vascular) as an example.” (see "Design principles and performance of bioresorbable polymeric vascular scaffolds." EuroIntervention: journal of EuroPCR in collaboration with the Working Group on Interventional Cardiology of the European Society of Cardiology 5 (2009): F15-22). Years later at a mid-2015 CME event (for which Abbott provided funding) in Maui, the keynote lecture was titled, “Bioresorbable Vascular Scaffold: The Fourth Revolution in Interventional Cardiology.” These are clear examples of Abbott’s pre-approval promotion in violation of 21 CFR 812.7.

65. Relator alleges that when these illegal promotional activities occurred, Abbott did not have a BVS investigational device exemption (IDE) for peripheral vascular use (e.g. superficial femoral artery) and that Abbott promoted BVS for treating peripheral vascular disease. Relator alleges that when these promotional activities occurred, Abbott did not have premarket approval for ANY BVS implant use and that the company was unauthorized to promote the device in any way. Abbott sent targeted promotional newsletters to physicians with contractual company relationships, including clinical trial investigators. This willful violation of a material precondition for payment renders all BVS clinical trial claims false and ineligible for federal funds of any kind (including Medicare reimbursement). Preapproval promotion is illegal solicitation to commit medical battery.

***False Statements of Material Fact***

66. Abbott's misconduct as a clinical trial sponsor violates human subject protection regulations and these violations have caused third parties to submit false statements to the government certifying compliance with human subject protection regulations.

***Material Misrepresentations made to CMS***

67. ABSORB III and ABSORB IV clinical trials were not conducted in compliance with human subject protection regulations so any certification of compliance with this requirement is false. Abbott was granted an Investigational Device Exemption for the investigation of BVS as a therapy for heart disease in the coronary artery in December 2012 based on a material misrepresentation of compliance with 21 CFR 812. The company illegally promoted the investigational BVS device before and after the IDE was granted. For this reason, the BVS IDE (G120002) itself is a false certification that attaches False Claims Act liability. CMS reliance on this false IDE certification is described in 42 CFR Part 405, Subpart B (titled "Medical Services Coverage Decisions That Relate to Health Care Technology"). IDE number G120002 is a false certification and CMS relied on Abbott's material misrepresentation in granting the coverage determination for ABSORB III and ABSORB IV.
68. Medicare coverage for the BVS clinical trials is subject to the requirements outlined in the National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1). Clinical trials that meet the qualifying criteria will receive Medicare coverage of routine costs after the trial's lead principal investigator

certifies that the trial meets the criteria. Therefore, at least two false certifications by lead investigators have been created due to Abbott's misconduct:

1. Lead principal investigator certification that the ABSORB III trial (NCT01751906) meets the qualifying criteria.
  2. Lead principal investigator certification that the ABSORB III PK trial (NCT02229864) meets the qualifying criteria.
  3. Lead principal investigator certification that the ABSORB IV trial (NCT02173379) meets the qualifying criteria.
69. Relator alleges the BVS clinical trial attestations made by these investigators contain false statements of material fact regarding the protection of human subjects:
1. Stephen G Ellis, MD (NPI 1679667208)  
Cleveland Clinic, Cleveland OH
  2. Dean J Kereiakes, MD (NPI 1427025055)  
The Christ Hospital, Cincinnati, OH
  3. Gregg W Stone, MD (NPI 1134206956)  
Columbia University Medical Center, New York, NY
  4. David G. Rizik, MD (NPI 1700862984)  
Scottsdale Healthcare, Scottsdale, AZ
  5. Louis A. Cannon, MD (NPI 1316960487)  
Cardiac and Vascular Research Center of Northern Michigan Petoskey, MI

70. According to Chapter 14 of the Medicare Benefit Policy Manual<sup>26</sup>, for purposes of Medicare coverage of items and services, an IDE study must meet specific criteria for which Abbott was knowingly and willfully noncompliant.

***Material Misrepresentations made to HHS - Federalwide Assurance (FWA)***

71. All federally-funded human research must comply with regulations for the protection of human subjects. Overstating the safety and efficacy of an investigational device exposes participating patients to unnecessary risk. A clinical trial is a type of human research. The HHS regulations under 45 CFR 46 were written to protect patients in studies that are conducted under an Investigational Device Exemption (IDE), as described in §46.102.
72. Pre-approval promotion allows a company to initiate new human research without mandatory oversight or informed consent. Abbott is manipulating clinical professionals' authority to off-label prescribe. Pre-approval promotion by a medical device company is illegal. Abbott benefits financially, however, when it circumvents human research requirements by manipulating a clinical professional's off-label prescribing authority. Abbott has overstated the safety and efficacy of investigational technology for uses in the heart and legs and, upon commercialization, doctors are free to use the implant for an unapproved use. Relator alleges that Abbott's fraudulent scheme has caused the FederalWide Assurance of BVS clinical trial sites (see Appendix B) to contain a false statement of material fact attesting that the BVS clinical trials are conducted in compliance with the Common Rule (45 CFR 46).

73. The Common Rule states that a violation of human subject protection regulations, including 21 CFR 812, is a violation of The Common Rule, as outlined in 45 CFR 46, subpart A, §46.101:

*“Compliance with this policy requires compliance with pertinent federal laws or regulations which provide additional protections for human subjects.”*

74. Abbott Laboratories knowingly violated 21 CFR 812.7, a human subject protection regulation, in the execution of human research studies:

ABSORB III Randomized Controlled Trial (NCT01751906)

ABSORB IV Randomized Controlled Trial (NCT02173379)

75. FDA oversight for the conduct of device research complements basic regulatory requirements for the protection of human subjects with the addition of specific regulatory requirements for devices. The requirements in 21 CFR 812 provide additional protections for human subjects. According to 45 CFR 46, subpart A, §46.122, Use of federal funds:

*“Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.”*

76. Both clinical trials, ABSORB III and ABSORB IV, are federally-supported human subject research because both studies are reimbursed by Medicare under the National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1). In other words, compliance with human subject protection regulations is a precondition of payment for ABSORB III and ABSORB IV. Abbott, however, has knowingly failed to comply by using various forms of misconduct, including

violations of 21 CFR 812, to secure payment for claims that are ineligible for federal funds. All Medicare payments annotated with “NCT01751906” or “NCT02173379” are false.

***False Claims***

77. Relator attended a clinical trial investigator's meeting in December 2012 where Abbott told study investigators that the best enrolling ABSORB III sites would be invited to participate in ABSORB IV. Representative false claims can be found by identifying claims after January 1, 2014, annotated with the national clinical trial number for ABSORB III or ABSORB IV for services at the clinical trial sites involved in both studies, as annotated in Appendix B. The BVS clinical trial described in a peer-reviewed publication reports that 2,008 patients of age of  $63 \pm 10$  years were enrolled, which means that hundreds of Medicare patients over age 65 years were enrolled and treated in the study beyond mere possibility (see Ellis, Stephen G., et al. "Everolimus-eluting bioresorbable scaffolds for coronary artery disease." *New England Journal of Medicine* 373.20 (2015): 1905-1915).
78. In December 2012 relator was invited to attend an Abbott meeting about clinical trial reimbursement, and relator has firsthand knowledge that Abbott held a meeting with Medicare in February 2013 to understand the required elements for obtaining federal reimbursement for BVS clinical trial claims. Relator also has firsthand knowledge that Medicare Administrative Contractors (MAC) approved coverage for BVS clinical trial claims because this information was tracked and reported in internal communications by the Clinical Research department.

79. Relator alleges:

1. that the BVS clinical trials contain a significant number of human subjects over age 65,
2. that Medicare claims for routine costs were submitted for BVS clinical trial patients,
3. that payment of those claims was conditioned upon compliance with an element of NCD 310.1 that was not met,
4. that those claims are false and fraudulent and those claims do not meet the definition of "reasonable and necessary" care because BVS clinical trials were not conducted in compliance with Federal regulations relating to the protection of human subjects.

***ABSORB III Randomized Controlled Trial (NCT01751906)***

80. False claims associated with this complaint cannot be accessed under the Freedom of Information Act. The post-2014 claims may be annotated with the FDA-granted investigational device exemption number ("G120002" for Absorb Bioresorbable Vascular Scaffold) and the national clinical trial number ("NCT01751906" for the ABSORB III Randomized Controlled Trial also called ABSORB-III).
81. The ABSORB III clinical trial has a national clinical trial number: "NCT01751906." Effective for Medicare claims with dates of service on or after January 1, 2014, it is mandatory to report this clinical trial number on claims for items/services provided in clinical trials. All claims that meet the new Medicare reporting requirement are false. ABSORB is a "category B" device and the

methodology for locating the false claims can be found within the Medicare Claims Processing Manual<sup>27</sup>:

"Providers report the 8-digit number on the following claims locators:

- CMS-1500 paper form-place in Field 19 (preceded by 'CT'); or
- 837 P—Loop 2300, REF02, REF01=P4 (do not use 'CT' on the electronic claim)...

Claims submitted without a clinical trial number shall be returned as unprocessable..."

82. The post-2014 claims may be annotated with the FDA-granted investigational device exemption (IDE) number ("G120002" for Absorb Bioresorbable Vascular Scaffold device) and/or the national clinical trial number ("NCT01751906" for the ABSORB III Randomized Controlled Trial also called ABSORB-III).
83. The Medicare Benefit Policy Manual states that claim information about an investigational device exemption is "proprietary in nature" and each Medicare "contractor must take appropriate action to ensure that the confidentiality of the information is protected." (see Medicare Benefit Policy Manual, Chapter 14 - Medical Devices, see Confidentiality of IDE Information). Due to the proprietary nature of IDE claims data, only the federal government is authorized to access the false claims associated with this qui tam complaint, which includes all claims on or after 01/01/2014 that are annotated with "G120002" and/or "NCT01751906."
84. The ABSORB III trial is a prospective randomized, single-blind, multi-center trial. It is the pivotal trial to support the US pre-market approval (PMA) of Absorb™ Bioresorbable Vascular Scaffold (BVS). The ABSORB III includes

additional two trials i.e. ABSORB III PK (pharmacokinetics) sub-study (NCT02229864) and ABSORB IV RCT trial which are maintained under one protocol because both trial designs are related, ABSORB IV is the continuation of ABSORB III and the data from ABSORB III and ABSORB IV will be pooled to support the ABSORB IV primary endpoint. Both the trials will evaluate the safety and effectiveness of Absorb BVS.

***ABSORB IV Randomized Controlled Trial (NCT02173379)***

85. Abbott announced enrolling patients in a second clinical trial under the same investigational device exemption in September 2014, about a month after reaktor's disclosure filing. Abbott continued to proactively disseminate illegal promotional material including a company newsletter titled "Pre-TCT 2014 -Absorb Fully Bioresorbable Vascular Scaffold (BVS): Emerging Real-World Clinical Data and Optimal Implant Techniques." All ABSORB IV Medicare claims in compliance with the Medicare Claims Processing Manual annotation are representative false claims. Due to the proprietary nature of IDE claims data, only the federal government is authorized to access the false claims associated with this qui tam complaint, which includes all claims on or after 01/01/2014 that are annotated with "G120002" and/or "NCT02173379."

***Fraud in the Inducement***

86. The federal government may avoid mounting damages by withdrawing the IDE and/or rejecting the scaffold PMA; denying Medicare reimbursement for the scaffold; or debarring Abbott altogether; however, if regulatory approval is granted and Medicare remains a payer, Abbott is liable under the False Claims

Act for all IDE number G120002-related scaffold claims under a FRAUD IN THE INDUCEMENT theory.

The government could limit Abbott's scheme to bilk the federal health care system by exercising its authority to:

- withdraw the Investigational Device Exemption (IDE) (see 21 CFR 812, section 812.30)
- deny FDA-approval (see 21 CFR 814, section 814.45)
- deny Medicare coverage (see Medicare Coverage Determination Process)
- exclude Abbott from participation in any Federal health care program (see Social Security Act section 1128)

87. The damages outlined in the original disclosure only estimate the financial scope of the fraud if the government *forfeits* these options by granting both regulatory approval and reimbursement.
88. Relator cannot calculate the exact amount of money charged to the federal government for the BVS clinical trials because IDE claims data are protected based on Medicare policies designed to safeguard the company's proprietary information. For this reason, relator based damages on Abbott's historic revenue data. The damages incurred due to Medicare reimbursement for human research leading up to FDA approval were not included in the original damages, but they must be added to the total. All claims associated with BVS clinical trial payments are false claims and they are evidence of damages incurred by the United States.
89. Federal funds were expended to support Abbott's human subject protection violations. The fraudulent scheme is based on Abbott's payments to parties who

then use the internet to disseminate illegal promotional material (wire fraud) that overstates the safety and efficacy of an investigational device that has no FDA-approved use. This promotional material is designed to manipulate clinical professionals into using their prescribing authority for the company's financial gain. Abbott violated the law by not complying with human subject protection regulations in order to be granted an investigational device exemption, which forms the basis for future device approvals. That exemption forms the basis for granting Medicare reimbursement for clinical trial costs.

90. Any device determined to be a significant risk or "SR device" by the FDA will remain so designated until the FDA rules otherwise. Studies using investigational SR devices are required to file an IDE with the FDA for approval before starting human research. Abbott is promoting BVS clinical use in the leg for a significant risk implant that was designed, but not FDA-approved, for treating heart disease. The company is conducting research for heart disease in pursuit of FDA-approval under an exemption, but by inciting clinicians to use the implant for another clinical application in the leg (peripheral disease), Abbott is initiating a new research study or "field experiment" into the use of a heart implant technology in the leg, without mandatory oversight and without valid informed consent (see 45 CFR 46, 21 CFR 50, 21 CFR 56, 21 CFR 812).
91. Abbott knowingly violated 21CFR812.7 even though compliance is a requirement for premarket approval (PMA) and a precondition for Medicare payment. Abbott's IDE number G120002 is a false certification of compliance with 21 CFR 812 and the company knowingly caused third-parties to make false statements to

get ineligible clinical trial claims reimbursed using federal funds. Due to this fraudulent conduct, all post-approval Medicare claims for any medical device based on PMA number P150023 (or any of its PMA supplements) that reference G120002 IDE study data are false claims. All BVS clinical trial Medicare claims on or after 01/01/2014 in compliance with the Medicare Claims Processing Manual annotations are representative false claims.

92. Relator alleges that in 2015 Abbott submitted an application for BVS premarket approval containing a false certification of compliance with 21 CFR 812 (refer to PMA number P150023). Elements of the regulatory application are outlined in 21 CFR 814:

*Unless the applicant justifies an omission in accordance with paragraph (d) of this section, a PMA shall include:*

*(6) The following technical sections which shall contain data and information in sufficient detail to permit FDA to determine whether to approve or deny approval of the application:*

*(A) A statement with respect to each study that it either was conducted in compliance with the institutional review board regulations in part 56, or was not subject to the regulations under 56.104 or 56.105, and that it was conducted in compliance with the informed consent regulations in part 50; or if the study was not conducted in compliance with those regulations, a brief statement of the reason for the noncompliance.*

*(B) A statement that each study was conducted in compliance with part 812 or part 813 concerning sponsors of clinical investigations and clinical investigators,*

or if the study was not conducted in compliance with those regulations, a brief statement of the reason for the noncompliance.

93. The documentary evidence in this qui tam complaint illustrates that the BVS clinical studies conducted under the G120002 exemption were not conducted in compliance with Part 812 of Code of Federal Regulations Title 21, which violates a material precondition for payment. BVS IDE (G120002) itself is a false certification that attaches False Claims Act liability. Consequently, False Claims Act liability attaches to all BVS claims for federal funds that rely on Abbott's false G120002 IDE certification for commercialization. As an example of how this type of early misconduct can have lasting implications, the XIENCE family of stents has a regulatory pathway linked to FDA approval under PMA number P070015 (see IDE number G050050), which has spawned more than 100 PMA supplements since 2008.

***Scheme and Artifice to Defraud***

94. Relator alleges that before the BVS IDE (G120002) was granted, Abbott conspired to and did illegally promote BVS in violation of human subject protection regulations. Abbott's fraudulent scheme includes paying a third-party to disseminate illegal promotional material electronically (wire fraud) via a third-party website in order to induce referrals. The egregious misconduct in this complaint includes presentations by paid Abbott employees at CME events funded by large Abbott grants. Abbott-funded grants or Abbott financial support to (or on behalf of) the conference provider, and any payments to (or on behalf of) employees developing and delivering illegal promotional materials, which are

intended to induce referrals paid for by federal programs, are kickbacks. Under the Anti-Kickback Statute, neither a legitimate purpose for an arrangement (e.g., physician education), nor a fair market value payment, will necessarily protect remuneration if there is also an illegal purpose such as pre-approval promotion of an investigational device in violation of 21 CFR part 812.

95. Abbott used proactive dissemination of illegal promotional material using newsletters via this third-party vendor:

Six Degrees LLC

8040 E Gelding Dr

Scottsdale, AZ

[www.six-degrees.com](http://www.six-degrees.com)

Abbott sponsors CME events with funding and, in exchange, receives the opportunity to have Abbott employees (typically executives) deliver promotional presentations in a CME forum to a targeted physician audience about the company's products (some of which are not FDA-approved). Abbott's employee-presenters are given a role as CME event "faculty" and their presentations are disseminated online as enduring materials. Conference events with illegal promotional presentations about Abbott products include:

Cardiovascular Research Technologies (CRT)

MedStar Heart Institute

MedStar Washington Hospital Center

110 Irving Street, NW

Suite 6-D

Washington, DC 20010

[www.crtonline.org](http://www.crtonline.org)

(CRT conference CME accreditation is established through MedStar Washington

Hospital Center: see [www.medstarhealth.org/gme/continuing-medical-](http://www.medstarhealth.org/gme/continuing-medical-education/medstar-washington-hospital-center/cme-services/)

[education/medstar-washington-hospital-center/cme-services/](http://www.medstarhealth.org/gme/continuing-medical-education/medstar-washington-hospital-center/cme-services/))

BioResorbable Vascular Scaffolds (BRS): Transformational Technology for PCI

Transcatheter Cardiovascular Therapeutics (TCT)

Cardiovascular Research Foundation (CRF)

111 East 59th Street, 11th floor

New York, NY 10022-1202

[www.crf.org](http://www.crf.org)

(TCT and BRS conference CME accreditation is established through CRF: see

[www.accme.org/find-cme-provider/cardiovascular-research-foundation](http://www.accme.org/find-cme-provider/cardiovascular-research-foundation))

Vascular Interventional Advances (VIVA) and LINC (this interventional course is endorsed by VIVA)

VIVA PHYSICIANS

5671 SANTA TERESA BLVD, SUITE 104

SAN JOSE, CA 95123

[vivaphysicians.org](http://vivaphysicians.org)

(VIVA conference CME accreditation is established through SUNY At Buffalo -

School of Medicine and Biomedical Sciences: see

[medicine.buffalo.edu/cme.html](http://medicine.buffalo.edu/cme.html))

VEITHsymposium

455 Douglas Ave

Bronx, NY 10471

veithsymposium.org

(VEITHsymposium conference CME accreditation is established through the Cleveland Clinic Center for Continuing Education: see [www.clevelandclinicmeded.com](http://www.clevelandclinicmeded.com))

96. Relator alleges that Abbott proactively disseminated these newsletters containing false and misleading statements to entities and individuals (see Appendix A) that have a financial relationship with the company to induce referrals of medical products (including, but not limited to, BVS and XIENCE) and services that are paid for by federal healthcare systems (Medicare and Medicaid):
  1. “Recent Clinical Data for Metallic Drug-Eluting Stents (DES) and Bare Metal Stents (BMS) from Major Meta-Analysis Studies” (Abbott routing number SE2939496 Rev. B 03/14)
  2. “Recent Clinical Data for Durable and Bioresorbable polymer Drug-Eluting Stents (DES) and Bare Metal Stents (BMS) from Major Meta-Analyses Studies” (Abbott routing number SE2940007 Rev. A 07/14)
  3. “Absorb™ Fully Bioresorbable Vascular Scaffold (BVS): Emerging Real-World Clinical Data and Optimal Implant Techniques” (Abbott routing number SE2940254 Rev. A 09/14)
  4. “Update on Absorb™ from TCT 2014” (Abbott routing number SE2940457 Rev. A 10/14)

5. “Major DAPT Randomized Trial Results at AHA and the CoCr-EES Subgroup Results” (Abbott routing number SE2940659 Rev. A)
  6. “Update on Supera®” (Abbott routing number SE2940556 Rev. A 11/14)
97. Relator alleges that recipients of the more than \$1 million in these transactions include targeted recipients (see Appendix A) of the illegal promotional materials because one purpose of Abbott’s payment was to induce referrals of Abbott medical products (including, but not limited to, BVS and XIENCE) and services that were paid using false claims submitted to the government, where each CMS Open Payments transaction identification number for Abbott Laboratories shown below constitutes a kickback from Abbott to the provider (see 2013 and 2014 data at <https://openpaymentsdata.cms.gov>):

102329972	102324752	102325344	22898086	102326612
102329808	102323508	102327206	102323050	22907208
102323398	22907888	102324046	22904100	22904478
22910065	22901747	102328872	22898847	102327746
22898999	22906015	102323480	22904869	102330304
22905909	102328252	22901049	22908480	22908072
22903211	102326210	102323802	102323456	195971396
102324740	102326788	102328906	22901582	195975818
102325420	22909963	102327752	22896422	195976800
102323918	102322384	102326708	102330360	195936696
102329928	102322116	102324460	22907147	196913228

195968794 195952006

195936728 196912330

195974360

195966944

195972712

195961792

195961794

195972714

195938266

195909794

196912734

195951948

195951950

195953072

195964356

195957748

195897486

195956790

195926176

195960038

195959870

195959874

195929836

98. Relator alleges that one purpose of these transactions to CME provider Medstar Washington Hospital Center was to induce false, fraudulent claims because the CME events from this sponsor were used as a platform for making and disseminating unsubstantiated promotional statements about Abbott medical products (including, but not limited to, BVS and XIENCE):

196912330

102322116

196913228

196912734

99. Specific illegal presentations, conference events, and speakers are described in the timeline that follows.

#### **D. RELEVANT TIMELINE**

100. Relator regularly attended the CME conference events in this timeline as a registered participant as part of her job, and she has firsthand knowledge of the information supporting her allegations. Relator alleges that disseminated presentations described in the following timeline are misleading because they contain promotional statements about Abbott products that are not accompanied by adequate FDA-approved labeling, and that Abbott paid the CME providers that disseminated these presentations, and that those payments made by Abbott to the CME providers are kickbacks (because one purpose of these payments was to induce false, fraudulent claims):

During 2007

- Abbott receives FDA warning letter<sup>28</sup> for promoting the Absolute Biliary Self-Expanding Stent System (Absolute biliary stent) for use in an unapproved indication at the Vascular Interventional Advances conference, VIVA 07, held September 25-28, 2007
- Boden, William E., et al.<sup>29</sup> "Optimal medical therapy with or without PCI for stable coronary disease." New England Journal of Medicine 356.15 (2007): 1503-1516.  
During 2008
- FDA sends Abbott premarket approval letter for XIENCE V (P070015) containing directives about thrombosis as a public health risk  
During 2009
- Abbott employee Lewis B. Schwartz, MD, presentation at CRT dated March 2009 titled: "DES Development for the SFA: The Abbott Program"<sup>30</sup>  
During 2010
- Abbott employee Lewis B. Schwartz, MD, presentation posted at CRTOnline.org dated December 2010 titled: "DES in the SFA: Will it ever work?"<sup>31,32</sup>  
During 2011
- Abbott initiates ABSORB BTK (Below The Knee) clinical trial (NCT01341340)<sup>33</sup> to evaluate ABSORB BVS for treating vessel disease of leg (tibial artery) (Discontinued due to poor enrollment)
- Abbott initiates ESPRIT I clinical trial to evaluate ESPRIT BVS (NCT01468974)<sup>34</sup> for treating vessel disease in the leg (superficial femoral artery (SFA) or common or external iliac artery)

- Abbott employee Richard J. Rapoza, PhD, presentation about the BVS device at TCT in November 2011 titled: “Bioabsorbable Stent Platforms: The Vision and New Questions in Eastern and Western Patients”<sup>35</sup>
- Abbott employee Lewis B. Schwartz, MD, presentation about the BVS device at VEITHsymposium in November 2011 titled: “Development Of Bioresorbable Scaffold Platforms For The Peripheral Vasculature: Can The Excellent Coronary Results Of The ABSORB TRIAL With Everolimus Polylactide Be Duplicated In Peripheral Arteries”<sup>36</sup>  
November 2012
- FDA approves first drug-eluting stent to treat peripheral arterial disease: Zilver PTX Stent is the first drug-eluting stent indicated to treat vessel blockage in the thigh (femoropopliteal artery) due to PAD<sup>37</sup>
- Abbott employee Richard J. Rapoza, PhD, gives CRT 2012 interview posted on February 23, 2012, at <http://www.cardiotube.net/?p=1919>
- Abbott employee Richard J. Rapoza, PhD, presentation about the BVS device at TCT in October 2012 titled “Development of a Bioresorbable Scaffold for the SFA”<sup>38</sup>
- Presentations about BVS device at VEITHsymposium in November 2012: <sup>39</sup>
  - Abbott employee Lewis B. Schwartz, MD, presentation about the BVS device at VEITHsymposium in November 2012, in a session called “Lower extremity additional topics,” titled: “Long-term results of the ABSORB trial showing benefits of biodegradable coronary stents: when will we know if they will work elsewhere”

- Dierk Scheinert, MD, presentation at VEITHsymposium, in a session called “Lower Extremity Hot Topics II,” in November 2012: “The many uses and advantages of the Supera Veritas Stent (IDEV) to treat femoropopliteal lesions”
- Dierk Scheinert, MD, presentation at VEITHsymposium, in a session called “Lower Extremity Hot Topics III,” in November 2012: “DEBATE: DEBs won’t do the job alone: stents will be needed sometimes for recoil or dissection” (DEB is “drug-eluting balloon,” also know as drug-coated balloon (DCB))  
  
December 2012
- FDA grants investigational device exemption G120002 for Absorb Bioresorbable Vascular Scaffold
- Abbott initiates ABSORB III (NCT01751906)<sup>40</sup> pivotal trial to support US pre-market approval (PMA) for ABSORB BVS for treating vessel disease in the coronary artery (heart disease)
- ABSORB III Investigator Meeting  
  
January 2013
- At the 2013 LINC meeting, 30-day results from the ESPRIT I trial were presented; Johannes Lammer, MD later describes ESPRIT I as a “first-in-man evaluation of the bioabsorbable, everolimus eluting vascular scaffold in peripheral arteries” during an interview<sup>41</sup>
- Abbott employee Richard J. Rapoza, PhD presentation at LINC 2013 describing BVS as the preferred solution for best outcomes compared to other devices for treating peripheral vessel disease in the leg (see slide titled “Clinical Impact of SFA Treatment Modalities”)<sup>42</sup>

February 2013

- Abbott employee Richard J. Rapoza, PhD presentation at CRT 2013 describing BVS as the preferred solution for best outcomes compared to other devices for treating peripheral vessel disease in the leg (see slide titled “Clinical Impact of SFA Treatment Modalities”)
- CRT 2013 brochure highlights topic titled "LINC at CRT" in the "Peripheral Arterial Disease & Critical Limb Ischemia" session<sup>43</sup>
- Abbott meeting with Medicare about obtaining clinical trial reimbursement for ABSORB III

March 2013

- Abbott employee Charles A. Simonton, MD, gives CRT 2013 interview where he expresses excitement about the “bioresorbable scaffold future as the next— what we’re calling the ‘Fourth Revolution of Coronary Angioplasty.’ ” (posted at <http://www.cardiotube.net/?p=2755>)

April to September 2013

October 2013

- Abbott employee Regina Deible presentation at VIVA 2013 (with no financial disclosure) describing BVS as the preferred solution for best outcomes compared to other devices for treating peripheral vessel disease in the leg (see slide titled “Clinical Impact of SFA Treatment Modalities”)

November 2013 to December 2013

January 2014

- Mandatory reporting of National Clinical Trial (NCT) identifier numbers on Medicare claims<sup>44</sup>
- LINC 2014 session supported with an "unrestricted educational grant" by Abbott Vascular<sup>45</sup>
- Abbott employee Richard J. Rapoza, PhD, presentation about the BVS device at LINC 2014 titled: "BVS – the future of PAD treatment" (see slide titled "Clinical Impact of SFA Treatment Modalities")<sup>46</sup>
- Dierk Scheinert, MD, presentation about the BVS device at LINC 2014 titled: "What's Next for SFA Treatment?" (see slide titled "Clinical Impact of SFA Treatment Modalities")<sup>47</sup>

February 2014

- Elliott-Lewis opened internal complaints under compliance report 1402ABT10003 and myHR ticket 8000765131 (reporting violation of Code of Federal Regulations Title 21, parts 801 and 812) to Abbott via Jim Curcio

March 2014

- Abbott Announces FDA Approval of Supera Stent to Treat PAD<sup>48,49</sup>
- Abbott Newsletter titled "Recent Clinical Data for Metallic Drug-Eluting Stents (DES) and Bare Metal Stents (BMS) from Major Meta-Analysis Studies" (see SE2939496 Rev. B 03/14)
- Abbott Medical Affairs leadership uses performance review process to direct Elliott-Lewis to "Increase ABSORB's penetration into PCI market " and "Establish Supera as market leading SFA stent" <sup>50,51,52,53</sup>

April 2014

- ABSORB III clinical trial enrollment ends<sup>54</sup>
- Abbott suspends Elliott-Lewis without pay because of her protected conduct

May 2014

- Elliott-Lewis internally reported False Claims Act violation to Abbott
- Abbott terminates Elliott-Lewis because of her protected conduct

June 2014

- Chowdhury MM et al<sup>55</sup> conclude there was no sustained benefit from primary stenting of lesions of the superficial femoral artery in addition to angioplasty

July 2014

- Capodanno et al conclude, “Real-world” outcomes of BVS showed acceptable rates of TLF at six months, although the rates of early and midterm scaffold thrombosis, mostly clustered within 30 days, were not negligible.”
- Abbott Newsletter titled “Recent Clinical Data for Durable and Bioresorbable polymer Drug-Eluting Stents (DES) and Bare Metal Stents (BMS) from Major Meta-Analyses Studies” (see SE2940007 Rev. A 07/14)
- Abbott employee Richard J. Rapoza, PhD, presentations about the BVS device at CME accredited conference event sponsored by the Cardiovascular Research Foundation (CRF) called “BioResorbable Vascular Scaffolds (BRS): Transformational Technology for PCI” (see <http://www.crf.org/brs>)<sup>56,57,58</sup>

August 2014

- Elliott-Lewis qui tam complaint filing

September 2014

- Abbott initiates ABSORB IV (NCT02173379)<sup>59,60</sup> clinical trial to evaluate ABSORB BVS as a treatment of subjects with heart disease (coronary artery lesions)
- Maharashtra FDA report includes details of overcharging by Abbott and Abbott Laboratories agreed to pay almost \$5.5 million to resolve allegations that the company paid kickbacks to induce doctors to implant the company's peripheral vascular products<sup>61</sup>
- Abbott Newsletter titled "Absorb Fully Bioresorbable Vascular Scaffold (BVS): Emerging Real-World Clinical Data and Optimal Implant Techniques"
- Abstract TCT-637: "Analysis of Quality of Life Decrements Associated with Changes in Angina Status in the ABSORB II Trial: First Randomized Comparison Between the Absorb\_ Everolimus Eluting Bioresorbable Vascular Scaffold and the XIENCE\_ Everolimus Eluting Stent" <sup>62</sup>

October 2014

- FDA approves first drug-coated angioplasty balloon catheter (DCB) to treat peripheral artery disease (PAD) in the leg (superficial femoral artery and popliteal artery)
- Abbott Newsletter titled "Update on Absorb from TCT 2014"
- Ielasi, A., et al. "Immediate and midterm outcomes following primary PCI with bioresorbable vascular scaffold implantation in patients with ST-segment myocardial infarction: insights from the multicentre" Registro ABSORB Italiano"(RAI registry)." EuroIntervention: journal of EuroPCR in collaboration

with the Working Group on Interventional Cardiology of the European Society of Cardiology (2014).<sup>63</sup>

November 2014

- Abbott Newsletter titled “Update on Supera”
- Abbott Newsletter titled “Major DAPT Randomized Trial Results at AHA and the CoCr-EES Subgroup Results”
- Regarding his 10/2014 article, Dr. Ielasi is quoted at tctmd.com: the strut dimensions that Abbott selected for the BVS design may represent “a potential trigger for a recurrent thrombosis in case of suboptimal BVS-to-vessel apposition and/or suboptimal platelet anti-aggregation.” (see <http://www.tctmd.com/show.aspx?id=127441>)<sup>64</sup>

December 2014

- Varcoe, RL presents “First Use of the ABSORB Bioresorbable Vascular Scaffold Below-the-Knee” followed by a Welcome Reception sponsored by a grant from Abbott at 2014 VERVE<sup>65</sup>
- Elliott-Lewis qui tam complaint unsealed

January 2015

- Abbott Laboratories (ABT) Earnings Report Q4 2014 Conference Call Transcript<sup>66</sup>: “We are also making regulatory progress with our bioresorbable vascular scaffold ABSORB, which we expect to submit for approval in the US, China, and Japan by the end of this year.”
- Brugaletta et al<sup>67</sup> conclude, “At 1-year follow-up, STEMI patients treated with BVS showed similar rates of device-oriented endpoint (DOCE) compared with

STEMI patients treated with EES or BMS, although rate of scaffolds thrombosis, mostly clustered in the early phase, was not negligible.”

February 2015

- Azzalini et al<sup>68</sup> conclude it can be speculated that the prothrombotic milieu of acute coronary syndrome (ACS), coupled with the unfavorable peristrut rheology of BVSs, might promote scaffold thrombosis early after implantation, particularly if other concomitant risk factors are present.
- Kawamoto et al<sup>69</sup> conclude that BVS is associated with a higher incidence of periprocedural myocardial infarction because of the strut dimensions that Abbott selected for the scaffold design (see Kawamoto, Hiroyoshi, et al. "Impact of Strut Width in Periprocedural Myocardial Infarction: A Propensity-Matched Comparison Between Bioresorbable Scaffolds and the First-Generation Sirolimus-Eluting Stent." JACC: Cardiovascular Interventions (2015))

March 2015

- Abbott employee Charles A. Simonton, MD gives CRT 2015 interview posted on March 5, 2015, at <http://www.cardiotube.net/?p=3886>

April 2015

- Varcoe, Ramon L., et al<sup>70</sup>. "Initial Experience With the Absorb Bioresorbable Vascular Scaffold Below the Knee Six-Month Clinical and Imaging Outcomes." Journal of Endovascular Therapy 22.2 (2015): 226-232.

May 2015

- Abbott Announces CE Mark for stent delivery system called Absorb GT1<sup>71</sup>

- Privately-held company Arterial Remodeling Technologies (“ART”)<sup>72</sup> announces CE Mark clearance for its scaffold used to treat coronary artery disease and CEO Machiel van der Leest explains, “Receiving the CE Mark for our Pure Bioresorbable Scaffold is a significant milestone for ART as we continue to develop this technology for the treatment of coronary artery and peripheral vascular disease.” Terumo acquired exclusive acquisition rights for the coronary drug eluting bioresorbable scaffold technology.
- Lewis B. Schwartz, MD, presentation at NCVH dated May 2015 titled: “Drug-Eluting Bioabsorbable Stents: Is This the Future of SFA and Popliteal Disease?”<sup>73</sup> June to August 2015
- Geoffrey O. Hartzler, MD Interventional Cardiology Symposium Program at The Sheraton Maui, Resort & Spa with keynote lecture titled: “Bioresorbable Vascular Scaffold: The Fourth Revolution in Interventional Cardiology” (see Simonton remarks from March 2013)<sup>74,75,76</sup>
- Abbott employee Richard J. Rapoza, PhD, presentation about the BVS device at CME accredited event called the 2015 CICT Conference<sup>77</sup>

***Unsubstantiated Superiority Statements***

101. Abbott conspired to make and did make unsubstantiated superiority statements in kickback-tainted CME settings about investigational heart disease technology for peripheral therapeutic use. In at least one instance, an Abbott employee acting as CME speaker failed to disclose any financial relationship with the company to the audience. Abbott brazenly uses grant funding and financial sponsorships as kickbacks to buy podium presence for company representatives. These speakers

- are then given CME faculty roles which they use to deliver promotional presentation materials containing false and misleading statements about Abbott products. This conduct represents direct industry influence over CME content, a practice that is strictly prohibited based on ACCME guidelines and OIG Guidance<sup>78,79</sup>. CME event organizers disseminated illegal promotional content as “enduring materials” on their websites, which is a form of wire fraud.
102. The Absorb BVS clinical trials are subject to FDA regulations (21 CFR parts 50, 56, and 812) because they are part of a study collecting evidence for premarket approval (PMA) of a new medical device. The studies must also comply with the Common Rule (45 CFR 46) because Medicare patients are participants in the study and federal funds from HHS (CMS) pay for their healthcare associated with the trial.
103. These Medicare clinical trial claims are “blessed” based on criteria outlined in the National Coverage Determination (NCD) for Routine Costs in Clinical Trials. Found in NCD 310.1 are the conditions that must be met for a clinical trial claim to qualify as “reasonable and necessary” and one of these is that the trial is conducted “in compliance with Federal regulations relating to the protection of human subjects.” CMS Medicare Benefits Policy Manual states that an eligible study must be “in compliance with all applicable Federal regulations concerning the protection of human subjects found at 21 CFR parts 50, 56, and 812, and 45 CFR part 46.”

*“For purposes of Medicare coverage of items and services in Category A and B IDE studies, an IDE study must meet all of the following criteria....*

*6. The study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 21 CFR parts 50, 56, and 812, and 45 CFR part 46.”*

104. In other words, compliance with these human subject protection regulations is a precondition for payment:
- 21 CFR part 50
  - 21 CFR part 56
  - 21 CFR part 812
  - 45 CFR part 46
105. This qui tam case contains flagrant violations of 21 CFR 812 (e.g. section 812.7) and the misconduct described was initiated before the first Medicare clinical trial claim was submitted. Because the BVS device is a class III, significant risk implant that is also a life sustaining device, full compliance with all elements of 21 CFR 812 is required in order to have a valid investigational device exemption (IDE); this compliance requirement was not met.
106. All clinical evaluations of investigational devices must have an approved IDE **before** the study is initiated. Unlike off-label promotion, preapproval promotion is an *expressly* prohibited act (see 21 CFR 812.7) under the FDCA that is subject to civil monetary penalties.

107. In this qui tam case, the violation of 21 CFR 812 is also a violation of 21 CFR parts 50 and 56, which are regulations for mandatory oversight and patient informed consent. A violation of 21 CFR 812 is a violation of human subject protection regulations and is, therefore, a violation of 45 CFR 46 (Common Rule). Under section 46.122, federal funds cannot be used to support violation of human subject protection regulations. This Federal Policy is the origin of the requirement in NCD 310.1 that the trial must be conducted “in compliance with Federal regulations relating to the protection of human subjects.”
108. All BVS clinical trial claims are false claims. The exemption granted under IDE number G120002, is a false certification of compliance with the conditions under 21 CFR part 812, a human subject protection regulation. All claims commercialized based on PMA number P150023 (or any of its PMA supplements) are also false claims because the application contains a false certification of compliance with human subject protection regulations, as required under 21 CFR 814.

***False and fraudulent off-label XIENCE claims were presented to the government for payment***

109. Relator alleges that the following XIENCE stent-related claims, which were submitted to the government for payment, are false due to due to Abbott’s willful off-label promotion and violation of the Anti-Kickback Statute:
- A. Patient A, with diagnosis code 250.XX, treated at MedStar Washington Hospital Center (District of Columbia), claim for drug-eluting stent with percutaneous transluminal coronary angioplasty (PTCA) in April 2014.

The claim was fraudulently induced by illegal off-label promotion of XIENCE for diabetics to the provider and these kickback payments from Abbott to the provider:

\$350,000.00	11/2014	see transaction 196912330
\$25,000.00	2/2014	see transaction 196912734
\$300,000.00	11/2013	see transaction 102322116

- B. Patient B, with diagnosis code 250.XX, treated in the state of New York, claim for drug-eluting stent with percutaneous transluminal coronary angioplasty (PTCA) in October 2014, where the claim contains NPI 1952343212. The claim was fraudulently induced by illegal off-label promotion of XIENCE for diabetics to the provider and these kickback payments from Abbott to the provider:

\$2,900.00	9/2014	see transaction 195952006
\$2,800.00	9/2014	see transaction 195929836

- C. Patient C, with diagnosis code 250.XX, treated in the state of New York, claim for drug-eluting stent with percutaneous transluminal coronary angioplasty (PTCA) in July 2014, where the claim contains NPI 1902894611. The claim was fraudulently induced by illegal off-label promotion of XIENCE for diabetics to the provider and these kickback payments from Abbott to the provider:

\$3,800.00	6/2014	see transaction 195959874
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- D. Patient D, with diagnosis code 250.XX, treated in the Commonwealth of Massachusetts, claim for drug-eluting stent with percutaneous transluminal coronary angioplasty (PTCA) in May 2014, where the claim contains NPI 1871528968. The claim was fraudulently induced by illegal off-label promotion of XIENCE for diabetics to the provider and these kickback payments from Abbott to the provider:

\$21,250.00      4/2014      see transaction 195926176

- E. Patient E, with diagnosis code 250.XX, treated in the state of Florida, claim for drug-eluting stent with percutaneous transluminal coronary angioplasty (PTCA) in April 2014, where the claim contains NPI 1134125347. The claim was fraudulently induced by illegal off-label promotion of XIENCE for diabetics to the provider and these kickback payments from Abbott to the provider:

\$2,300.00      3/2014      see transaction 195956790

- F. Patient F, with diagnosis code 250.XX, treated in the state of California, claim for drug-eluting stent with percutaneous transluminal coronary angioplasty (PTCA) in April 2014, where the claim contains NPI 1063449403. The claim was fraudulently induced by illegal off-label promotion of XIENCE for diabetics to the provider and these kickback payments from Abbott to the provider:

\$2,500.00      3/2014      see transaction 195897486

- G. Patient G, with diagnosis code 250.XX, treated in the state of Michigan, claim for drug-eluting stent with percutaneous transluminal coronary

angioplasty (PTCA) in April 2014, where the claim contains NPI 1689642415. The claim was fraudulently induced by illegal off-label promotion of XIENCE for diabetics to the provider and these kickback payments from Abbott to the provider:

\$2,000.00      3/2014      see transaction 195957748

- H. Patient H, with diagnosis code 250.XX, treated in the state of Arizona, claim for drug-eluting stent with percutaneous transluminal coronary angioplasty (PTCA) in April 2014, where the claim contains NPI 1700862984. The claim was fraudulently induced by illegal off-label promotion of XIENCE for diabetics to the provider and these kickback payments from Abbott to the provider:

\$3,000.00      3/2014      see transaction 195953072

- I. Patient I, with diagnosis code 250.XX, treated in the District of Columbia, claim for drug-eluting stent with percutaneous transluminal coronary angioplasty (PTCA) in April 2014, where the claim contains NPI 1134170459. The claim was fraudulently induced by illegal off-label promotion of XIENCE for diabetics to the provider and these kickback payments from Abbott to the provider:

\$6,000.00      3/2014      see transaction 195951950

- J. Patient J, with diagnosis code 250.XX, treated in the state of Florida, claim for drug-eluting stent with percutaneous transluminal coronary angioplasty (PTCA) in April 2014, where the claim contains NPI 1710990908. The claim was fraudulently induced by illegal off-label promotion of XIENCE

for diabetics to the provider and these kickback payments from Abbott to the provider:

\$3,600.00      3/2014      see transaction 195951948

***False and fraudulent clinical trial claims were presented to the government for payment***

110. In an interview reported on March 4, 2013, Dean Kereiakes, MD, Medical Director for The Christ Hospital Heart and Vascular Center and for The Carl and Edyth Lindner Center for Research and Education at The Christ Hospital in Cincinnati, confirmed that claims were submitted to Medicare for the ABSORB clinical trial with this statement (see Disappearing Act! Dissolving Heart Stents-- In-Depth Doctor's Interview [http://search.ivanhoe.com/channels/p\\_channelstory.cfm?storyid=30937](http://search.ivanhoe.com/channels/p_channelstory.cfm?storyid=30937)):
- “In fact, the first one we did the hospital didn’t get reimbursed from CMS or Medicare. It took doing the procedure and informing Medicare. Medicare administrators have to become knowledgeable about these things and they have to be informed of the protocol. They are usually supportive, but there is often a time lag. These technologies are not going to cost them more than the usual approved technology that would be used as an alternative.”*
111. Study information found at [clinicaltrials.gov](http://clinicaltrials.gov) describes use of coronary angiography in evaluating “Acute Success” during the timeframe “from the start of index procedure to end of index procedure.” As of July 2013, there were 83 Absorb trial sites, 77 of those sites had Medicare Administrative Contractor approval for reimbursement of routine clinical trial costs under NCD 310.1 and

there were 161 randomized subjects. The Clinical Research department asked senior executives to personally contact study sites with lower than expected enrollment. The 16 sites selected for the special calls were among the first 40 sites to implant Absorb in the US and each of these sites enrolled at least 1 patient. See the email exchange in Exhibit A. Relator alleges that the following claims, which were submitted to the government for payment by Medicare, are false due to Abbott's knowing and willful violation of federal human subject protection regulations:

1. Patient 1, claim for cardiac catheterization between December 2012 and July 2013 at Washington Hospital (Fremont, CA) where the claim contains the 8-digit clinical trial number 01751906 and/or IDE number G120002
2. Patient 2, claim for cardiac catheterization between December 2012 and July 2013 at Rochester General Hospital (Rochester, NY) where the claim contains the 8-digit clinical trial number 01751906 and/or IDE number G120002
3. Patient 3, claim for cardiac catheterization between December 2012 and July 2013 at Abbott Northwestern Hospital (Minneapolis, MN) where the claim contains the 8-digit clinical trial number 01751906 and/or IDE number G120002
4. Patient 4, claim for cardiac catheterization between December 2012 and July 2013 at UMass Memorial Medical Center (Worcester, MA) where the claim contains the 8-digit clinical trial number 01751906 and/or IDE number G120002

5. Patient 5, claim for cardiac catheterization between December 2012 and July 2013 at Presbyterian Hospital (Charlotte, NC) where the claim contains the 8-digit clinical trial number 01751906 and/or IDE number G120002
6. Patient 6, claim for cardiac catheterization between December 2012 and July 2013 at Hillcrest Medical Center (Tulsa, OK) where the claim contains the 8-digit clinical trial number 01751906 and/or IDE number G120002
7. Patient 7, claim for cardiac catheterization between December 2012 and July 2013 at Thomas Hospital (Fairhope, AL) where the claim contains the 8-digit clinical trial number 01751906 and/or IDE number G120002
8. Patient 8, claim for cardiac catheterization between December 2012 and July 2013 at Saint Joseph's Hospital of Atlanta (Atlanta, GA) where the claim contains the 8-digit clinical trial number 01751906 and/or IDE number G120002
9. Patient 9, claim for cardiac catheterization between December 2012 and July 2013 at Cleveland Clinic (Cleveland, OH) where the claim contains the 8-digit clinical trial number 01751906 and/or IDE number G120002
10. Patient 10, claim for cardiac catheterization between December 2012 and July 2013 at St. Francis Health System (Greenville, SC) where the claim contains the 8-digit clinical trial number 01751906 and/or IDE number G120002

11. Patient 11, claim for cardiac catheterization between December 2012 and July 2013 at St. Vincent's Medical Center (Bridgeport, CT) where the claim contains the 8-digit clinical trial number 01751906 and/or IDE number G120002
12. Patient 12, claim for cardiac catheterization between December 2012 and July 2013 at Mercy Hospital Springfield (Springfield, MO) where the claim contains the 8-digit clinical trial number 01751906 and/or IDE number G120002
13. Patient 13, claim for cardiac catheterization between December 2012 and July 2013 at East Texas Medical Center (Tyler, TX) where the claim contains the 8-digit clinical trial number 01751906 and/or IDE number G120002
14. Patient 14, claim for cardiac catheterization between December 2012 and July 2013 at Anmed Health (Anderson, SC) where the claim contains the 8-digit clinical trial number 01751906 and/or IDE number G120002
15. Patient 15, claim for cardiac catheterization between December 2012 and July 2013 at Oklahoma Heart Hospital (Oklahoma City, OK) where the claim contains the 8-digit clinical trial number 01751906 and/or IDE number G120002
16. Patient 16, claim for cardiac catheterization between December 2012 and July 2013 at Medical Center of the Rockies (Denver, CO) where the claim contains the 8-digit clinical trial number 01751906 and/or IDE number G120002

112. As of January 2014, CMS instituted mandatory reporting of the 8-digit clinical trial number on a claim for payment. As explained in Exhibit A, only study sites with strong enrollment (defined by Abbott as enrolling one patient per week) for ABSORB III were invited to participate in ABSORB IV. Ten ABSORB III sites were identified for the special calls due to low enrollment, but they were later invited to participate in ABSORB IV, indicating that enrollment improved to meet the company expectations. Abbott announced the completion of enrollment for ABSORB III in a press release dated April 2014. Relator alleges that the following claims, which were submitted to the government for payment by Medicare, are false due to Abbott's knowing and willful violation of federal human subject protection regulations:

17. Patient 17, claim for cardiac catheterization between January 2014 and March 2014 at Washington Hospital (Fremont, CA) where the claim contains the 8-digit clinical trial number 01751906
18. Patient 18, claim for cardiac catheterization between January 2014 and March 2014 at Rochester General Hospital (Rochester, NY) where the claim contains the 8-digit clinical trial number 01751906
19. Patient 19, claim for cardiac catheterization between January 2014 and March 2014 at Abbott Northwestern Hospital (Minneapolis, MN) where the claim contains the 8-digit clinical trial number 01751906
20. Patient 20, claim for cardiac catheterization between January 2014 and March 2014 at Presbyterian Hospital (Charlotte, NC) where the claim contains the 8-digit clinical trial number 01751906

21. Patient 21, claim for cardiac catheterization between January 2014 and March 2014 at Thomas Hospital (Fairhope, AL) where the claim contains the 8-digit clinical trial number 01751906
22. Patient 22, claim for cardiac catheterization between January 2014 and March 2014 at Cleveland Clinic (Cleveland, OH) where the claim contains the 8-digit clinical trial number 01751906
23. Patient 23, claim for cardiac catheterization between January 2014 and March 2014 at Mercy Hospital Springfield (Springfield, MO) where the claim contains the 8-digit clinical trial number 01751906
24. Patient 24, claim for cardiac catheterization between January 2014 and March 2014 at East Texas Medical Center (Tyler, TX) where the claim contains the 8-digit clinical trial number 01751906
25. Patient 25, claim for cardiac catheterization between January 2014 and March 2014 at Anmed Health (Anderson, SC) where the claim contains the 8-digit clinical trial number 01751906
26. Patient 26, claim for cardiac catheterization between January 2014 and March 2014 at Medical Center of the Rockies (Denver, CO) where the claim contains the 8-digit clinical trial number 01751906
113. Abbott announced the ABSORB IV clinical trial in a press release dated September 2014 and the clinical study continued under an additional clinical trial number. Ten ABSORB III sites were identified for the special calls due to low enrollment, but they were later invited to participate in ABSORB IV, indicating

that enrollment improved to meet the company expectations. Relator alleges that the following claims, which were submitted to the government for payment by Medicare, are false due to Abbott's knowing and willful violation of federal human subject protection regulations:

27. Patient 27, claim for cardiac catheterization between between November 2015 and December 2015 at Washington Hospital (Fremont, CA) where the claim contains the 8-digit clinical trial number 02173379
28. Patient 28, claim for cardiac catheterization between November 2015 and December 2015 at Rochester General Hospital (Rochester, NY) where the claim contains the 8-digit clinical trial number 02173379
29. Patient 29, claim for cardiac catheterization between November 2015 and December 2015 at Abbott Northwestern Hospital (Minneapolis, MN) where the claim contains the 8-digit clinical trial number 02173379
30. Patient 30, claim for cardiac catheterization between November 2015 and December 2015 at Presbyterian Hospital (Charlotte, NC) where the claim contains the 8-digit clinical trial number 02173379
31. Patient 31, claim for cardiac catheterization between November 2015 and December 2015 at Thomas Hospital (Fairhope, AL) where the claim contains the 8-digit clinical trial number 02173379
32. Patient 32, claim for cardiac catheterization between November 2015 and December 2015 at Cleveland Clinic (Cleveland, OH) where the claim contains the 8-digit clinical trial number 02173379

33. Patient 33, claim for cardiac catheterization between November 2015 and December 2015 at Mercy Hospital Springfield (Springfield, MO) where the claim contains the 8-digit clinical trial number 02173379
34. Patient 34, claim for cardiac catheterization between November 2015 and December 2015 at East Texas Medical Center (Tyler, TX) where the claim contains the 8-digit clinical trial number 02173379
35. Patient 35, claim for cardiac catheterization between November 2015 and December 2015 at Anmed Health (Anderson, SC) where the claim contains the 8-digit clinical trial number 02173379
36. Patient 36, claim for cardiac catheterization between November 2015 and December 2015 at Medical Center of the Rockies (Denver, CO) where the claim contains the 8-digit clinical trial number 02173379

#### **E. SUMMARY**

114. Relator alleges that Abbott conspired to and did engage in the off-label promotion of its FDA-approved drug eluting stent XIENCE for use in patients with diabetes mellitus in March 2014, which is evidence of intent to misbrand, and that Abbott introduced misbranded XIENCE stents into interstate commerce from March 2014 to September 2015.
115. Relator alleges that Abbott conspired to and did engage in the pre-approval promotion of its BVS implant before FDA granted the IDE for BVS. BVS, however, is not an FDA-approved device. Unlike “off-label promotion,” “preapproval promotion” creates an unavoidable risk of serious harm that cannot

be eliminated by the use of due care. In fact, risk mitigation strategies like mandatory oversight (by FDA and IRBs) and patient informed consent are unavailable when a company incites doctors to prescribe a device that is not FDA-approved for a use *other than* the intended use. Abbott manufactures BVS in the United States and, since the devices did not comply with 21 CFR 812, the company introduced adulterated BVS devices into interstate commerce for international sale (Class III device that fails to meet PMA requirements is considered to be adulterated under section 501(f) of the FD&C Act (see also section 351(f) and 351(i) of the FD&C Act) and cannot be marketed).

***Retaliation and Violation of Public Policy Rule***

116. Relator never resigned from her employment with Abbott. She asked repeatedly, in writing, to utilize leave to which she was fully entitled. Abbott Laboratories discriminated against her when the company violated its own leave policy and then wrongfully terminated her. In February 2014, relator filed a corporate compliance complaint alleging violations of 21 CFR 812 and 21 CFR 801 and she was issued Report number 1402ABT10003 (see also Employee Relations ticket number 8000765131). At the time of her submission, relator genuinely believed that promoting an unapproved medical implant was a criminal violation, so she filed the complaint to document her concerns and met with compliance officer Jeff Berry.

117. Abbott Laboratories corporate manager Jim Curcio was assigned to investigate her internal report. Relator alleged in her internal complaint that her managers were retaliating against her for refusing to engage in illegal conduct, including

illegal promotion of both the XIENCE stent and the unapproved BVS implant. In writing, her managers directed her to increase market penetration of the unapproved medical implant, which is illegal. Her refusal to engage in the illegal promotion is a protected activity. In her email to Curcio dated 03/21/2014, relator wrote, “Even though my supervisors used my review to imply that I do not belong in Medical Affairs, I have no intention of resigning.” In her email to Curcio dated 04/24/2014, relator wrote, “Abbott has not addressed my original complaint and I have neither resigned nor abandoned my position.” Consistent with the company policy, while on approved leave under the Family and Medical Leave Act (FMLA), relator made two written requests to Curcio to be placed on paid leave dated 04/30/2014 and 05/02/2014. Abbott Laboratories manager Jim Curcio wrongfully terminated her employment on 05/09/2014.

118. Because of relator’s protected conduct, Abbott and Curcio retaliated by terminating her with accrued, paid leave despite her reasonable request. Curcio violated the company “Vacation” policy found at Document ID C-196, which says:

*Abbott provides vacation benefits on a “look forward” basis and employees do not earn vacation on a pro rata basis, but instead receive a lump sum allowance of vacation at the beginning of the calendar year for that coming year.*

119. Curcio also violated the company “Family Leave of Absence” (FLOA) policy found at Document ID C-503, which says:

*Employees on an unpaid FLOA may, but will not be required to, use vacation or holiday credits while on a FLOA.*

*Employees who have an approved FLOA may recertify their FLOA prior to the expiration of the existing approved FLOA if an eligible absence has occurred within 30 days or is expected to occur within 30 days of the expiration date.*

120. Relator engaged in additional protected conduct on 04/30/2014, when she reported to Jim Curcio, in writing, that the company's regulatory violations implicate the False Claims Act, when she stated, "... within OEC Report number 1402ABT10003, I reported definitive evidence of an egregious, company supported federal False Claims Act and Anti-Kickback Statute violation. Next the company suspended my pay, which is yet another retaliatory and, therefore, illegal personnel action."
121. In addition to her request to use her accrued paid leave, Relator saw her primary care physician on May 8, 2014, to obtain medical certification for an FMLA extension. Abbott violated FMLA federal regulations found at 29 CFR part 825, which state that the employer "must allow at least 15 calendar days" for medical recertification (see section 825.308). Instead Jim Curcio wrongfully terminated Relator the next day for putting Abbott Laboratories on notice of the False Claims Act violation when, without completing the internal investigation she had initiated in February 2014, he plainly stated in an email to Relator dated May 9, 2014, "I will inform your manager that your employment is terminated effective 05-09-14." Relator further alleges that, after terminating her because of her protected conduct, Abbott retaliated against her post-employment by contesting her state unemployment benefits claim.

122. Relator alleges that Abbott Laboratories wrongfully terminated her because of her protected conduct, which included her refusal to participate in the illegal promotion of XIENCE and the unapproved BVS implant and her internal reporting that regulatory violations of 21 CFR 801 and 21 CFR 812 implicate the False Claims Act. Relator alleges that before the first applicable Medicare claim was submitted, Abbott knowingly and willfully promoted an unapproved medical implant called BVS in violation of Federal human subject protection regulations, even though compliance is a material precondition for payment as defined in NCD 310.1. Consequently, Abbott caused submitting entities shown in Appendix B to submit false claims for payment to the United States government for routine costs in BVS clinical trials described under the identifiers “NCT01751906” and “NCT02173379.”
123. Abbott’s fraudulent scheme is expansive and the company’s misconduct proliferated after Relator’s internal compliance report, wrongful termination, and qui tam filing. Even after being explicitly informed of specific regulatory violations and the False Claims Act implications, Abbott continued engaging in the same misconduct she outlined. Abbott Laboratories wrongfully terminated Relator for reporting the misconduct.<sup>80</sup> Abbott willfully failed to bring the organization into compliance as required by law.<sup>81, 82, 83, 84, 85, 86</sup>
124. Abbott conspired to and did knowingly misrepresent compliance with a material precondition of payment and that precondition was labeled as such. Abbott's pre-approval promotion of an investigational heart disease technology for treating vessel disease in the leg allows the company to usurp the human agency of each

patient implanted with its new scaffold device. Abbott illegally promoted the XIENCE stent for diabetic patients with the intent to induce false and fraudulent claims. Abbott attempted to subvert the regulatory approval process by using illegal promotion tactics that exposed patients to unnecessary risk. Relator presented documentary evidence of fraud initiated during what is likely the most nascent stage in the introduction of a new medical device, a device that is also a significant risk implant that presents a potential for serious risk to the health, safety, or welfare of a patient. False Claims Act enforcement is warranted given Abbott's extensive history of liberal illegal promotion and the egregious, reprehensible nature of these more recent violations, which include noncompliance with a material precondition for payment using federal funds known as the Common Rule.

### **COUNT I**

#### **United States of America and Relator, Ebonia Elliott-Lewis, Against Abbott for Violations of 31 U.S.C. §3729 False Claims Act**

125. The Relator, Elliott-Lewis, repeats and restates the allegations contained in paragraphs 1 through 124 and incorporate said allegations herein by reference.
126. Pursuant to 31 U.S.C. §3729, any person who
  - (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
  - (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent;

(C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);

(D) has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property;

(E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(F) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge property; or

(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government, is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains because of the act of that person.

(2) **REDUCED DAMAGES.**—If the court finds that—

(A) the person committing the violation of this subsection furnished officials of the United States responsible for investigating false claims violations with all information known to such person about the violation within 30 days after the date on which the defendant first obtained the information;

(B) such person fully cooperated with any Government investigation of such violation; and

(C) at the time such person furnished the United States with the information about the violation, no criminal prosecution, civil action, or administrative action had commenced under this title with respect to such violation, and the person did not have actual knowledge of the existence of an investigation into such violation, the court may assess not less than 2 times the amount of damages which the Government sustains because of the act of that person.

(3) COSTS OF CIVIL ACTIONS.—A person violating this subsection shall also be liable to the United States Government for the costs of a civil action brought to recover any such penalty or damages.

127. The Defendant has violated §3729 on multiple occasions by providing false and misleading information to the United States government. Specifically, the Defendant knowingly presented or caused to be presented false or fraudulent claims for payments or approvals including, but not limited to violation of False Claim Act regulations, anti-kickback regulations, marking false therapeutic claims, and unlawful promotion during the pre and post-approval process. These violations include violations of 21 C.F.R 801.4 and 21 C.F.R 812.7

128. The Defendant knowingly made, used or caused to be made or used false records or statements material to a false or fraudulent claim.
129. The Defendant conspired to commit and did commit violations of subparagraph (A), (B), (C), (E) and/or (G).
130. More specifically the Defendant engaged in conduct which was deceitful and intentionally misleading by failing to have policies and procedures in place to ensure all applicable government regulations and requirements were met including, but not limited to, proper anti kick-back policies implemented and enforced in violation of §3729 and the Anti Kick-back Statute, off-label marketing and pre and post approval marketing.

WHEREFORE, the Relator, Elliott-Lewis demands judgment against the defendant, in an amount that this Honorable Court shall deem just and proper, together with attorneys fees, costs, interest and punitive damages.

**COUNT II**

**United States of American and Relator, Ebonia Elliott-Lewis, Against Abbott for  
Violations of 42 U.S.C. § 1320a-7b  
Anti-Kickback Statute**

131. The Relator, Elliott-Lewis, repeats and restates the allegations contained in paragraphs 1 through 129 and incorporate said allegations herein by reference.
132. Abbott has engaged in conduct which violates Sunshine Laws and 42 U.S.C. §1320a-7b (Anti Kick-back Statute) by engaging in conduct that improperly seeks special arrangements between Abbott and medical providers in exchange for special or preferential treatment in violation of federal law.

WHEREFORE, the Relator, Elliott-Lewis demands judgment against the defendant, in an amount that this Honorable Court shall deem just and proper, together with attorneys fees, costs, interest and punitive damages.

**COUNT III**

**Relator, Ebonia Elliott-Lewis, Against Abbott for Retaliation in Violation of U.S.C. Section 3730(h)**

133. The Relator, Elliott-Lewis, repeats and restates the allegations contained in paragraphs 1 through 132 and incorporate said allegations herein by reference.
134. At all relevant times Elliott-Lewis was engaged in protected activity for raising concerns about the marketing and sales tactics used by Abbott, which he believed to be illegal and improper. In retaliation for her complaints, Abbott improperly terminated Elliott-Lewis on May 9, 2014.

WHEREFORE, the Relator, Elliott-Lewis, demands judgment against the defendant, in an amount that this Honorable Court shall deem just and proper, together with attorneys fees, costs, interest and punitive damages.

**COUNT IV**

**Violation of Public Policy Except to Employees at Will**

135. The Relator, Elliott-Lewis, repeats and restates the allegations contained in paragraphs 1 through 134 and incorporate said allegations herein by reference.
136. At all relevant times Relator was an employee at will for Abbott. In or about February 2014, Relator complained about and reported numerous violations of Federal safety laws intended to protect the health and safety of persons in the U.S. and filed a formal corporate compliance complaint with the Abbott Laboratories Office of Ethics and Compliance. Following direction from human resources, she

filed a separate personnel complaint with Employee Relations (corporate human resources) on February 20, 2014. As a result she was wrongfully discharged in retaliation for her complaints.

137. At all relevant times there were established public policies regarding the health and welfare of participants in medical clinical trials that required all companies engaged in these clinical trials to comply with all applicable Federal laws regarding the health and welfare of study participants.
138. After Relator reported her concerns regarding Abbott's violations of these public policies, Abbott terminated her employment on or about May 9, 2014 in violation of the Public policy rule governing employees at will.

WHEREFORE, the Relator, Elliott-Lewis, demands judgment against the defendant, in an amount that this Honorable Court shall deem just and proper, together with attorneys fees, costs, interest and punitive damages.

Respectfully Submitted,  
The Plaintiff,  
By Her Attorney,

/s/ David P. Angueira  
David P. Angueira, Esq.  
BBO No.: 019610  
Swartz & Swartz, P.C.  
10 Marshall Street  
Boston, MA 01208  
(617) 742-1900

Dated: July 8<sup>th</sup>, 2016

**APPENDIX A – NATIONAL PROVIDER IDENTIFIERS (NPI) FOR SOLICITED PHYSICIANS**

1407943582	1386619575	1245320076	1922096494
1861472367	1831101708	1649289976	1588655922
1942250717	1063596930	1811931264	1992714851
1396777827	1972595536	1306948302	1679532311
1508851510	1851551238	1952343212	1538195664
1740364801	1942244413	1245224625	1942294673
1255373692	1821095134	1821040478	1346391869
1326127267	1619934924	1053398198	1740219062
1922072693	1275585846	1154315778	1346246626
1346290046	1528060936	1659361095	1952460826
1316942782	1538161187	1902872740	1023086691
1144214735	1881621100	1396722252	1306803630
1134104144	1194717348	1790714251	1235135708
1023094117	1548268790	1013917962	1407828817
1629150768	1972547974	1215936653	1902870512
1366436818	1720052715	1255381778	1316938723
1427090257	1154344919	1710990908	1659579274
1093719015	1316914047	1184712622	1619943263
1396739009	1386638153	1851384192	1871677930
1134170459	1760453344	1558462770	1730192709
1376572933	1114987997	1508867383	1548210768

1376533562	1366542284	1023006269	1457328403
1942280672	1245302314	1861495558	1982648317
1427025055	1952383846	1447279237	1275539702
1497798078	1619931847	1710925300	1093787889
1871598235	1861435406	1467421164	1235106766
1316910466	1003811563	1861485104	1598736126
1679511554	1275527707	1366435810	1598734337
1861614638	1306888144	1508808304	1174593461
1205872850	1528058773	1487676938	1316956857
1477661429	1295845444	1366460974	1831118157
1740266725	1922111905	1689651416	1033144258
1861482556	1003942830	1548263361	1457563702
1184676413	1033161138	1144212770	1104984632
1316960487	1679602627	1508808593	1730237553
1104810076	1083612378	1134327745	1336132182
1497704191	1043287832	1295717205	1790786648
1679512479	1700862984	1629173133	1194781674
1639148745	1992776264	1952391518	1093755944
1902899305	1427118579	1740265032	1568452738
1881673234	1043265978	1134185390	1063474468
1639123789	1255415121	1922038298	1760431837
1356358741	1710067368	1720008360	1497729123
1942237326	1316986474	1275567661	1639172885

1689673998	1215965298	1831154798	1003909300
1316929359	1669475778	1700920139	1811917073
1346387198	1649278011	1972752467	1881683365
1669449203	1427000959	1073520128	1104827856
1356441497	1649369661	1144219973	1851307755
1255352738	1821070780	1891771440	1407830847
1396743860	1447369368	1184627333	1326007477
1679503783	1962483099	1013972488	1134206956
1679667208	1063449403	1831197813	1720079247
1558302638	1427044858	1659336790	1720165640
1790737633	1063408227	1851369813	1841279684
1780625269	1659758845	1013901081	1902894611
1174554851	1730187063	1669422960	1548269053
1639143951	1073622031	1568548006	1184624645
1609820919	1568490464	1164450235	1720003494
1710921085	1427138395	1205875002	1699851071
1780688705	1174509160	1376504795	1699718130
1578539201	1891790978	1396751889	1215937446
1083659486	1144290636	1598730269	1568496677
1063407203	1184673303	1316005333	1033176466
1225086416	1356436638	1326019563	1205910189
1871528968	1689642415	1760418230	1154401206
1760494272	1508828591	1114179264	1780630038

1437156429

1902066871

1134125347

1124322516

**APPENDIX B – CLINICAL TRIAL SITES FOR ABSORB III RANDOMIZED  
CONTROLLED TRIAL (NCT01751906) AND ABSORB IV RANDOMIZED  
CONTROLLED TRIAL (NCT02173379)**

row	INSTITUTION	FWA (Federalwide	ZIP CODE
		Assurance)	
1	Abbott Northwestern Hospital	FWA00002425	55407
2	Advocate Christ Medical Center	FWA00000472	60453
3	Allegheny General Hospital	FWA00015120	15212
4	Anmed Health	FWA00000630	29621
5	Aultman Hospital	FWA00003115	44710
6	Banner Heart Hospital	FWA00000043	85206
7	Baptist Hospital of Miami	FWA00017830	33176
8	Baptist Medical Center - Downtown	FWA00001001	32207
9	Barnes Jewish Hospital	FWA00002284	63110
10	Baylor Heart and Vascular Hospital	FWA00004415	75204
11	Beaumont Hospitals	FWA00002516	48073
12	Bethesda North Hospital	FWA00003114	45242
13	Boone Hospital Center	FWA00003837	65201
14	Boston Medical Center	FWA00000301	02118
15	Brandon Regional Hospital	FWA00000148	33511
16	Brigham and Women's Hospital	FWA00000484	02115
17	Bryn Mawr	FWA00001169	19010

18	Carilion Roanoke Memorial Hospital	FWA00000392	24014
19	Carolinas Medical Center	FWA00000387	28203
20	Carolinas Medical Center-Pineville	FWA00000388	28210
21	Cedars-Sinai Medical Center	FWA00000468	90048
22	Chandler Regional Medical Center	FWA00001499	85224
23	Christiana Care Health Services	FWA00006557	19713
24	Cleveland Clinic Foundation	FWA00005367	44195
25	Columbia University Medical Center	FWA00003831	10032
26	Cooper University Hospital	FWA00000211	08103
27	Dartmouth Hitchcock Memorial Hospital	FWA00003095	03756
28	Doylestown Hospital	FWA00004803	18901
29	East Texas Medical Center	FWA00006044	75701
30	Eastern Maine Medical Center	FWA00000604	04401
31	Elkhart General Hospital	FWA00009238	46514
32	Emory University Hospital	FWA00005792	30322
33	Englewood Hospital and Medical Center	FWA00008369	07631
34	Franciscan St. Francis Health	FWA00001662	46237
35	Geisinger Medical Center	FWA00000063	17822
36	Genesis Good Samaritan Hospital	FWA00004432	43701
37	Good Samaritan Hospital	FWA00005636	90017
38	Greenville Memorial Hospital	FWA00001380	29605
39	Harper University Hospital	FWA00002459	48201
40	Heart Hospital of New Mexico	FWA00003517	87102

41	Holy Cross Hospital	FWA00003747	33308
42	Holy Spirit Hospital	FWA00005059	17011
43	Inova Fairfax Hospital	FWA00000573	22042
44	Integrus Baptist Medical Center	FWA00003082	73112
45	Jewish Hospital	FWA00002167	40202
46	John Muir Medical Center	FWA00003748	94520
47	Little Company of Mary Hospital	FWA00006916	90503
48	Long Island Jewish Medical Center	FWA00002505	11030
49	Loyola University Medical Center	FWA00009471	60153
50	Maine Medical Center	FWA00003993	04102
51	Mayo Clinic	FWA00005001	55902
52	Medical Center of the Rockies	FWA00003977	80538
53	MedStar Washington Hospital Center	FWA00000504	20782
54	Memorial Regional Hospital	FWA00003898	33021
55	Mercy Hospital - Springfield	FWA00006466	65804
56	Mercy St. Vincent Medical Center	FWA00001831	43608
57	Montefiore Medical Center	FWA00002558	10467
58	Morton Plant Hospital	FWA00011037	33756
59	Mount Sinai Medical Center	FWA00005656	10029
60	Munroe Regional Medical Center	FWA00010113	34471
61	Nebraska Heart Hospital	FWA00003720	68526
62	Northeast Georgia Medical Center	FWA00000130	30501
63	Northwest Texas Healthcare System	FWA00003086	79106

64	Northwestern Memorial Hospital	FWA00001550	60611
65	Oakwood Hospital	FWA00003005	48124
66	Ochsner Clinic	FWA00002050	70121
67	Ohio State University	FWA00006378	43210
68	Our Lady of Lourdes Medical Center	FWA00021085	08103
69	Palm Beach Gardens Medical Center	FWA00009903	33410
70	Pennsylvania Hospital	FWA00004028	19107
71	Piedmont Hospital Atlanta	FWA00000662	30309
72	Presbyterian Hospital	FWA00018652	28204
73	Providence St. Vincent Medical Center	FWA00001033	97225
74	Rex Hospital	FWA00000740	27607
75	Rochester General Hospital	FWA00000966	14621
76	Scripps Memorial Hospital	FWA00007338	92037
77	Seton Medical Center Austin	FWA00004937	78705
78	Sharp Memorial Hospital	FWA00000084	92123
79	Spectrum Health	FWA00000058	49506
80	St. Joseph Mercy Hospital	FWA00000188	48197
81	St. Joseph's Hospital	FWA00003906	98225
82	St. Luke's Episcopal Hospital	FWA00021512	77030
83	St. Patrick Hospital	FWA00002065	59802
84	St. Vincents Medical Center	FWA00006526	32204
85	Stanford Hospital and Clinics	FWA00000934	94305
86	Stony Brook Hospital and Medical Center	FWA00000125	11794

87	Strong Memorial Hospital	FWA00009386	14642
88	Sutter Memorial Hospital	FWA00001330	95819
89	Tallahassee Memorial Hospital	FWA00006166	32308
90	The Christ Hospital	FWA00000702	45219
91	The Methodist Hospital	FWA00000438	77030
92	The Miriam Hospital	FWA00003538	02906
93	Thomas Hospital	FWA00016878	36532
94	Torrance Memorial Medical Center	FWA00004254	90505
95	UC Davis Medical Center	FWA00004557	95817
96	University of Florida - Jacksonville	FWA00005790	32209
97	Vanderbilt University Medical Center	FWA00005756	37232
98	Wake Med	FWA00000213	27610
99	Washington Hospital	FWA00004753	94538
100	Wellmont Holston Valley Medical Center	FWA00004221	37660
101	Winchester Medical Center	FWA00007424	22601
102	Yale-New Haven Hospital	FWA00002577	06510

- <sup>1</sup> REG 21 CFR 50
- <sup>2</sup> REG 21 CFR 56
- <sup>3</sup> REG 21 CFR 812
- <sup>4</sup> REG Common Rule\_45 CFR 46 subpart A
- <sup>5</sup> REG NCD 310.1\_Routine Clinical Trial
- <sup>6</sup> GUIDANCE Publications on Risk Information
- <sup>7</sup> GUIDANCE OIG Compliance\_April 2003
- <sup>8</sup> GUIDANCE Defining Promotion\_OIG on Pre-Approval Promotion Activities
- <sup>9</sup> GUIDANCE Unsolicited Requests
- <sup>10</sup> GUIDANCE Unapproved New Uses
- <sup>11</sup> GUIDANCE IDE Benefit-Risk Determinations
- <sup>12</sup> TALK Rapoza at LINC 2013
- <sup>13</sup> TALK Rapoza schedule at CRT 2013
- <sup>14</sup> TALK Deible at VIVA 2013
- <sup>15</sup> Washington Hospital\_Open Payments Data 2013
- <sup>16</sup> PMA XIENCE p070015a
- <sup>17</sup> CMO ABSORB\_PreTCT Sept 2014
- <sup>18</sup> CMO ABSORB\_PostTCT Oct 2014
- <sup>19</sup> CMO DAPT PostAHA Nov 2014
- <sup>20</sup> CMO Meta-Analyses July 2014
- <sup>21</sup> CMO SUPERA PostVIVA Nov 2014
- <sup>22</sup> Journal\_Eurointervention\_Capodanno et al
- <sup>23</sup> FDA approves first drug-coated balloon to treat PAD
- <sup>24</sup> Medicare OIG Anti-Kickback Provisions
- <sup>25</sup> Social Security Act §1128B
- <sup>26</sup> Medicare Benefit Policy Manual
- <sup>27</sup> Medicare Claims Processing Manual
- <sup>28</sup> Warning letter 2007 \_ Abbott
- <sup>29</sup> Journal Boden et al COURAGE
- <sup>30</sup> 2009 CRT\_Lewis B Schwartz
- <sup>31</sup> 2010 CRT\_final program
- <sup>32</sup> 2010 CRT\_Lewis B Schwartz
- <sup>33</sup> Clinical Trial ABSORB BTK
- <sup>34</sup> Clinical Trial ESPRIT I\_ ESPRIT BVS
- <sup>35</sup> 2011 TCT-Program
- <sup>36</sup> 2011 VEITH\_Program
- <sup>37</sup> Press Release\_ FDA approves first drug-eluting stent to treat peripheral arterial disease
- <sup>38</sup> 2012 TCT\_Focus on India
- <sup>39</sup> 2012 VEITH\_Program
- <sup>40</sup> Clinical Trial ABSORB III
- <sup>41</sup> Johannes Lammer, MD interview\_ESPRIT I Bioresorbable Vascular Scaffold 30-Day Study Results
- <sup>42</sup> LINC\_Review\_2013
- <sup>43</sup> LINC at CRT 2013\_brochure
- <sup>44</sup> Mandatory-Clinical-Trial-Identifier-Number-QsAs
- <sup>45</sup> LINC 2014t\_Abbott grant disclosure\_Jan 2014
- <sup>46</sup> LINC 2014t\_Richard\_Rapoza
- <sup>47</sup> LINC 2014\_Scheinert
- <sup>48</sup> Press Release\_Abbott Announces FDA Approval of Its Supera Stent to Treat PAD
- <sup>49</sup> PMA SUPERA P120020a
- <sup>50</sup> TMS goals 1
- <sup>51</sup> TMS goals 2
- <sup>52</sup> TMS goals 3
- <sup>53</sup> TMS goals 4
- <sup>54</sup> Press Release-Abbott Completes Enrollment of Absorb
- <sup>55</sup> Journal\_cochraneREVIEW on stent in SFA

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<sup>56</sup> 2014 BRS\_disclosure  
<sup>57</sup> 2014 BRS\_presentations  
<sup>58</sup> 2014 BRS\_CME event  
<sup>59</sup> Clinical Trial ABSORB IV  
<sup>60</sup> Press Release-Abbott Initiates ABSORB IV Trial  
<sup>61</sup> Maharashtra-Food-And-Drug-Administration\_Profits from medical devices used to bribe doctors  
<sup>62</sup> ABSTRACT\_ABSORB Angina  
<sup>63</sup> JOURNAL\_Bioresorbable Scaffolds in STEMI  
<sup>64</sup> INTERVIEW\_Bioresorbable Scaffolds in STEMI  
<sup>65</sup> VERVE Dec 2014  
<sup>66</sup> Transcript - Abbott Laboratories (ABT) Earnings Report Q4 2014  
<sup>67</sup> Journal\_JACC Intervention\_BVS examination  
<sup>68</sup> Journal\_J Invasive Cardiology\_Azzalini  
<sup>69</sup> JOURNAL Impact of strut width in periprocedural myocardial infarction  
<sup>70</sup> Journal\_J Endovasc Ther-2015-Varcoe  
<sup>71</sup> Press Release-Abbott announces ABSORB GT1  
<sup>72</sup> NEWS\_Arterial Remodeling Technologies (ART) Announces CE Mark Clearance for its Pure Bioresorbable Scaffold  
<sup>73</sup> 2015 NCVH\_Lewis Schwartz  
<sup>74</sup> 2015 Geoffrey O. Hartzler symposium  
<sup>75</sup> 2015 Geoffrey O. Hartzler\_venue  
<sup>76</sup> 2015 Geoffrey O. Hartzler\_CME  
<sup>77</sup> CICT\_2015\_Brochure\_Rapoza  
<sup>78</sup> GUIDANCE 07292009\_oig\_testimony  
<sup>79</sup> GUIDANCE CORPORATE RESPONSIBILITY CORPORATE COMPLIANCE  
<sup>80</sup> EEL Wrongful Termination  
<sup>81</sup> <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS012673.html>  
<sup>82</sup> 12062010 Finance Committee Staff Report on Cardiac Stent Usage at St Joseph Medical Center  
<sup>83</sup> Appropriateness Criteria for Coronary 2009  
<sup>84</sup> GUIDANCE Promotion\_Final Guidance on Industry-Supported Scientific and Educational Activities  
<sup>85</sup> Code of Conduct OLD  
<sup>86</sup> Code of Conduct NEW